Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Annex to the Background document

to the Opinion on the Annex XV dossier proposing restrictions on

Terphenyl, hydrogenated

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ECHA/RAC/RES-O-0000007224-79-01/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

IUPAC NAME(S): Terphenyl, hydrogenated

EC NUMBER(S): 262-967-7

CAS NUMBER(S): 61788-32-7

10/03/2023

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LIST OF ACRONYMS AND ABBREVIATIONS

CLH	Harmonised Classification and Labelling
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
COM	European Commission
CSP	Concentrated Solar Power
CSR	Chemical Safety Report
C/E	Cost-effectiveness
C&L	Classification and Labelling
DP	Dechlorane Plus
EAC	Equivalent Annual Cost
ECHA	European Chemicals Agency
EEA	European Economic Area
EEE	Electrical and electronic equipment
EiF	Entry into Force
EPA	Environmental Protection Agency
ERC	Environmental Release Category
EU	European Union
GDP	Gross domestic product
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HTF	Heat Transfer Fluid
ISS	Istituto Superiore di Sanità - Italy
IU	Identified Uses
LR	Lead Registrant
NILU	Norwegian Institute for Air Research

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NIVA	Norwegian Institute for Water Research
OC	Operational Condition
OECD	Organisation for Economic Co-operation and Development
OR	Only Representative
ORC	Organic Rankine Cycle
PBT	Persistent, Bioaccumulative and Toxic
PC	Product Category
PEC	Predicted Environmental Concentration
PET	Polyethylene terephthalate
PROC	Process Category
RAC	Risk Assessment Committee
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measures
RMO	Regulatory Management Option
RMOA	Regulatory Management Option Analysis
RO	Restriction Option
SCIP	Substances of Concern In articles as such or in complex objects (Products)
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SDS	Safety Data Sheet
SME	Small and Medium-sized Enterprises
SpERC	Specific Environmental Release Category
STP	Sewage Treatment Plant
SU	Sector of Use
SVHC	Substance of Very High Concern

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UK	United Kingdom
USA	United States of America
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bioaccumulative
WWTP	Wastewater Treatment Plant

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Annex A: Manufacture and uses

A.1. Manufacture, import and export

Companies are responsible for collecting information on the properties and uses of Terphenyl, hydrogenated, if they manufacture or import the substance into the European Union (EU) above one tonne per year. This information is communicated through a registration dossier under the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1].

According to the information from the REACH registration on the European Chemicals Agency (ECHA) public dissemination website (ECHA, 2021a)[2], there are currently 6 active registrants of Terphenyl, hydrogenated. The Lead Registrant (LR), Eastman Chemical BV, registered the substance in 2010, the other five co-registrants registered it by the 2018 deadline. At least two of those member-registrants are assumed to be Only Representatives (OR), representing non-EU companies. The last update of the registration dossier was carried out by the LR in 2020.

The list of active registrations is as follows:

Table 1. REACH registrations

Registrant - Supplier	Country	Status	Registered	Updated
Eastman Chemical BV	Netherlands	LR	2010	2014; 2018; 2020
3M Belgium BVBA/SPRL	Belgium	Member Registrant	2018	2019
FRAGOL AG	Germany	Member Registrant	2018	2018; 2019
GCP Produits de Construction S.A.S	France	Member Registrant	2018	2018
LANXESS Distribution GmbH	Germany	Member Registrant	2018	
PPG Europe B.V.	Netherlands	Member Registrant	2018	

All these registrations are full registrations, according to Article 10 of the REACH Regulation.

The amount of Terphenyl, hydrogenated manufactured and imported into the EU is, according to registration data on the ECHA public dissemination website (ECHA, 2021a), in the range of 10 000 - 100 000 tonnes per year. This is diverging from the volumes reported by industry.

Information collected during stakeholder consultations, via interviews and questionnaires (as set out on **Annex G** (Stakeholder Information) reveals, that since the United Kingdom (UK) has left the EU, no manufacturing of Terphenyl, hydrogenated is taking place in the EU anymore.

Based on information received from stakeholders, the global volume of Terphenyl, hydrogenated manufactured in 2020 is approximately 32 000 tonnes per year, and the total volume imported in 2020 into the EU is assumed to be in the order of 7 500 tonnes per year. The EU volume of 7 500 tonnes per year includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year. A significant number of notification to the

[1] Regulation (EC) No. 1907/2006 (REACH Regulation). Consolidated version 01/03/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20220301&qid=1646849873367

[2] https://echa.europa.eu/registration-dossier/-/registered-dossier/15941

SCIP database (> 12 000 entries, status on 2 March 2022) were reported in the Substances of Concern In articles as such or in complex objects (Products) (SCIP) Database (ECHA, 2021b) In December 2022 in total more than 24.000 entries in the SCIP database containing Terphenyl, hydrogenated have been notified. It is proven that mixtures containing Terphenyl, hydrogenated can be ordered via Internet, for example from the United States of America (USA) to the EU. Moreover, the stakeholder information received indicates that some of the registrants are importing mixtures from non-EU countries into the EU and have therefore conducted a REACH registration.

Table 2 shows the estimated volumes and the global trend in the years 2018 – 2020. Manufacturers of Terphenyl, hydrogenated are located in the UK (Eastman), in the USA (Eastman), in China (e.g., Armcoltherm, Jiangsu Zhongneng Chemical) and in Saudi-Arabia (Farabi Petrochemicals). The trend in the EU and globally shows a significant increase of volume during the last two years, (approximately 25% from 2018 to 2019 and approximately 36% from 2019 to 2020 in the EU).

The Danish Environmental Protection Agency (EPA) referenced in its report[3] a steady growth in the Heat Transfer Fluid (HTF) market. This was confirmed by feedback during the public consultation.

Table 2. Estimated volumes globally and in the EU, based on stakeholder information

	Terphenyl, hydrogenated Volume Manufactured Globally (tonnes per year)		
	2020	**2019**	**2018**
Total Volume (tonnes per year)	32 000	25 000	23 000
Increase in %	28	9	-
	Terphenyl, hydrogenated Volume in EU (tonnes per year) – incl. in Articles imported		
	2020	**2019**	**2018**
Total Volume (tonnes per year)	7 500	5 500	4 400
Increase in %	36	25	-

The manufacturing process as taken from the literature is described under **Annex B.1.1**.

A.2. Uses

An overview of registered uses of Terphenyl, hydrogenated from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a) is presented below.

- Manufacture
- Uses as intermediate:
  - None
- Formulation:
  - Formulation, transfer, and packing of substances in preparations and mixtures
  - Formulation of adhesives and sealants
  - Formulation of coatings or inks

[3] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net).

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    - Formulation – use as additive in plastic applications
- Uses at industrial sites
    - Use as HTF
    - Use as adhesive and sealants
    - Use as solvent or process medium
    - Use for coatings or inks applications
    - Use as additive in plastic application
    - Use in laboratory analysis
- Uses by professional workers
    - Use as HTF – no longer relevant. Please refer to footnote[4]
    - Use as adhesive and sealants
    - Use for coatings or inks applications
    - Use in laboratory analysis
- Consumer uses
    - None (uses advised against)
- Article service life (articles solely used by workers)
    - Articles produced from use as plasticiser
    - Articles produced from use of coatings and inks
    - Plastic articles
- Article service life (articles used by consumers)
    - Consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves

The main use of Terphenyl, hydrogenated (approximately 90% of the tonnage according to the stakeholder feedback) is as HTF. A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater). Selection of the most suitable HTF is based on the type of industrial applications, stable temperature range for safe operation and lifetime of the HTF. Synthetic HTFs like Terphenyl, hydrogenated do not require pressurizing at temperatures up to 350°C. Another advantage of using a mineral or synthetic fluid, as opposed to water, is that it generally has a lower freezing point. Lastly, HTFs also tend to be less reactive and corrosive to pipes and other parts of the system than water.

If Terphenyl, hydrogenated is used as HTF it is used as such. Formulation activities also including repacking are not relevant for the main use of Terphenyl, hydrogenated as HTF.

The use described as "use in laboratory analysis", where small amounts of in-use HTF is analysed to determine its lifetime, is also related to the HTF uses in industrial set-ups.

The use of the substance as a plasticiser is the second relevant use, involving around 10% of the tonnage range. Plasticisers are additives that increase the plasticity or decrease the

[4] In December 2022, the LR has analysed his database to determine at how many sites HTF is used in a professional setting. Thereby, it was determined that all sites receiving Terphenyl, hydrogenated as HTF are indeed industrial sites. Hence, the use of Terphenyl, hydrogenated as HTF at professional sites is no longer regarded as relevant.

viscosity of a material. Terphenyl, hydrogenated is used as a plasticiser mainly for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, sealants, and adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, Terphenyl, hydrogenated is also used as plasticiser in coatings and inks.

Very little information regarding the use of Terphenyl, hydrogenated, mainly as plasticiser, for the production of coatings, paints and inks, and as additive in plastic applications, was provided in the different public consultations (official and unofficial) issued for this substance: the LR SEA questionnaire from 2018, the socio-economic impact questionnaire from COM on 2020, the responses to the 10th Recommendation received by ECHA in 2020, and the DS SEA questionnaire from 2021. Also, no information regarding these uses can be found via internet search.

As commented in **Annex D.2.**, the decreasing participation in the SEA questionnaires from 2018 to 2021 suggests that the industry involved in these uses has already started the reformulation/substitution process of the substance. But no information is available regarding the alternative substances used in substitution.

The remaining registered uses (both industrial and professional) involve less than 1% of the amount of substance imported into the EU. Consumer uses and intermediate uses have not been registered.

Based on the information obtained through the analysis of the SCIP database the consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves[5] or of electrical capillary thermostats was identified (further information below).

Based on information received from stakeholders, **Table 3** was prepared showing the EU volumes used for the main applications of Terphenyl, hydrogenated in the EU. The HTF use accounts for approximately 6 700 tonnes per year, reflecting approximately 90% of the total EU volume used. The non-HTF uses represent approximately 10% of the total volume. Plasticiser uses in sealants, adhesives, castings, and coating make-up for more than 9% of the non-HTF uses, while < 1% remains to processing solvents, corrosion inhibitor oils and laboratory chemicals (e.g., analytical standards, immersion oils).

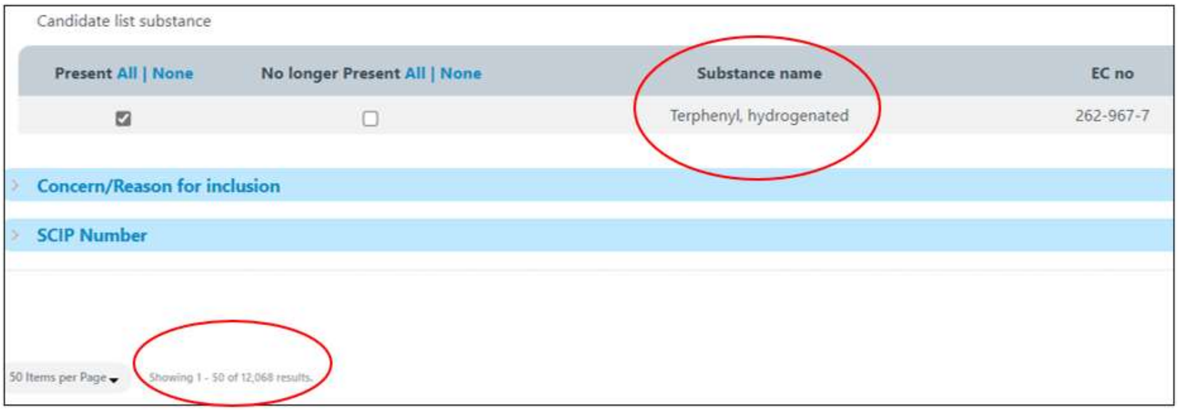
The SCIP database (ECHA, 2021b) was checked on 2 March 2022. In total more than 12 000 entries containing Terphenyl, hydrogenated have been notified to this database. Most entries are related to use in polymers, rubber & elastomers (> 60%), sealants (> 25%), inks (> 5%), sensors (< 1%), paper (> 1%) and a few others. In summary it can be concluded that around 85% of Terphenyl, hydrogenated use in articles is related to plasticiser uses. The Dossier Submitter assumes that some additional Terphenyl, hydrogenated volume will be entering the EU via articles, due to the high number of notifications in SCIP. The information obtained though analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

The DS does not know what exactly the additional uses (15%) are and would therefore ask that this is being clarified during the Public Consultation. Besides consulting the SCIP Database, a comprehensive internet search was conducted to identify additional applications in articles. Moreover, it cannot be excluded that the remaining 15% are as well plasticizer uses but were not notified accordingly in the SCIP database.

According to our understanding, the unclear uses are not of importance, otherwise responses should have been received during the different stakeholder consultations. It is not expected that a full ban will have a severe impact.

[5] REACH - Information on critical substances (miele.co.uk)

Figure 1. Number of notifications to the SCIP database on articles including Terphenyl, hydrogenated (Status March 2022)



In December 2022, the SCIP Database had a total number of almost 25 000 database entries (or factsheets).

The article categories notified were reported as follows:

- Measuring instruments and apparatuses
- Electrical machinery and equipment and components thereof
- Machinery and mechanical appliances and components thereof
- Base metals and articles thereof
- Vehicles, aircraft, vessels and associated transport equipment and parts thereof
- Articles of stone, plaster, cements
- Plastics and articles thereof
- Products of the chemical or allied industries
- Pulp of wood or of other fibrous cellulosic material
- Miscellaneous manufactured articles
- Textiles and textile articles, knitted or crocheted fabrics

Uses of terphenyl hydrogenated in mixtures are reported in the SCIP database in cases where the mixture become part of the article (e.g. coated articles) with an integral mixture.

Suppliers of articles notified that Terphenyl, hydrogenated was for example included in adhesives and sealants but also in printing inks and toners. The use of Terphenyl, hydrogenated as HTF in domestic appliances and electrical machinery was reported as well. The use of Terphenyl, hydrogenated in these cases is as HTF in the electromechanical temperature controls of ovens and stoves[6] or of electrical

The materials category notified is dominated by polymers, like silicones, rubbers, epoxies, polyurethanes, phenolic resins. In general, these materials are used for adhesives and sealants. In addition, metals were reported as components, where Terphenyl, hydrogenated containing articles were used.

The Dossier Submitter assumes that articles notified to the SCIP database are small and parts

[6] REACH - Information on critical substances (miele.co.uk)

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of very complex products, like vehicles (cars, trains, planes), Electrical and Electronic Equipment (EEE), construction and building components, or furnishings. Complex products are products, which are composed of multiple components which can be replaced permitting disassembly and re-assembly of the product.

An internet search by the Dossier submitter found 66 Safety Data Sheets (SDSs) in EU and USA format for non-HTF products, mainly plasticiser formulations. The concentration levels of Terphenyl, hydrogenated within these mixtures are ranging from < 1 to 60%.

Table 3. Split of volumes per use in the EU based on information provided by stakeholders

EU Uses	**Volume (tonnes per year)**	**%**
HTF	**6 700**	**89.68**
Industrial Adhesives, Castings, Sealants	300	4.02
Aerospace Coatings	250	3.35
Aerospace Sealants	180	2.41
Processing Solvent or Aids	35	0.47
Corrosion Inhibitor Oils	4	0.05
Analytical Standards	1	0.01
Microscope Immersion Oils	0.5	0.01
Total non-HTF	**771**	**10.31**

As shown above, the main use of Terphenyl, hydrogenated with approximately 90% annual tonnage is as a high-temperature non-pressurised HTF. When used as an HTF, Terphenyl, hydrogenated is a significant utility chemical for EU manufacturing of polyethylene terephthalate (PET) and other polymers, the conversion of biomass to energy, chemicals, and energy production in closed loop manufacturing systems.

Table 4 outlines the use as HTF and it shows the estimated EU installed base in existing plants handling Terphenyl, hydrogenated for this use. This information is based on feedback from the stakeholder consultations and individual communications. The assumed EU-wide installed base is approximately 25 000 tonnes. In 2020 approximately 6 700 tonnes of Terphenyl, hydrogenated were sold on the EU market, from which around 5% were used for "top-up". The top-up or refill demand is driven by the degradation rate of the HTF and the separated low-boiling and high-boiling degradation products. It needs to be understood that the refill cannot be associated with loss of Terphenyl, hydrogenated into the environment. Approximately 34% of that volume (2 275 tonnes) was used for replacements of the whole Terphenyl, hydrogenated in existing plants, at the point when the HTF had to be completely exchanged and disposed of. The life cycle was reported with >20 years. 58% (approximately 3 900 tonnes) account for filling new installed plants in the EU.

The degradation rate of the system is determined by the sum of degraded fluid.

Table 4. Installed base in the EU and uses as HTF

Use of HTF volumes on annual base		
	Tonnes	%
Installed Base in EU	25 000	-
Total volume sold in 2020	6 700	
Top-up existing plants	325	5

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Replacement existing plants	2 275	35
Filling new plants	3 900	60

According to the data obtained from stakeholders, the total number of closed loop manufacturing systems using Terphenyl, hydrogenated as HTF in the EU is close to 1,300 systems, which are installed in 24 of the 27 EU Member States. Around 40% of the plants have an installed capacity of < 10 tonnes, which is pointing to the use of systems in Small and Medium-sized Enterprises (SME) companies, approximately 50% are in the range of systems with > 10 to < 50 tonnes and less than 10% are > 50 tonnes.

Table 6 provides an overview on the number of systems installed and installed volume per EU Member State. Italy, Germany, and France are covering 70% of the volume and 75% of the systems.

Table 5 shows the distribution of the EU HTF use to the different application sectors. The total amount of installed volume is slightly higher compared to **Table 6** since the UK volumes are still included in this table. The highest percentage of HTF use is in the manufacturing of chemicals, specialty chemicals and petrochemicals. It should be noted that approximately 20% of Terphenyl, hydrogenated is already used in renewable energy processes. Concentrated Solar Power (CSP) is an innovative technology to transfer heat from the solar collectors to the power cycle. Organic Rankine Cycle (ORC) are considered to be a next generation technology as well for power generation from residual heat, for example for cost-effective power generation using waste or biomass heat from combustion or production processes.

The waste heat evaporates an organic working fluid when temperatures are still relatively low and drives a generator in a closed thermal circuit. The heat used for ORC power generation can then be employed in further processes, for example for heating purposes.

CSP and ORC are both innovative technologies for renewable energy generation. Other HTF uses include manufacturing of polymers, metals, oil and gas processing, process equipment heating, energy recovery, food processing and wood processing.

Table 5. Installed HTF Volume by application sector in 2017

EU HTF Volume installed by Application Sector (2017) (incl. UK)		
Application	**Installed volume (tonnes)**	**%**
Chemicals, Specialties and Petrochemicals	11 900	48.08
Renewable Energy (e.g. ORC, CSP)	5 350	21.62
Polymers & Plastics (incl. PET)	5 000	20.20
Oil and Gas Processing	1 300	5.25
Process Equipment Heating (Food, Aluminium, Wood)	1 200	4.85
Total installed Volume	**24 750**	**100**

The heat used for ORC power generation can then be employed in further processes, for example for heating purposes. CSP and ORC are both innovative technologies for renewable energy generation. Other HTF uses include manufacturing of polymers, metals, oil and gas

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processing, process equipment heating, energy recovery, food processing and wood processing.

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Table 6. Installed HTF volume and number of sites in 2018 per EU Member State

Member State	No. of Systems	Volume (t)	Systems > 50 t (%)	Systems >10<50 t (%)	Systems <10 t (%)
Austria	40 - 50	730 - 750	**10**	**50**	**40**
Belgium	40 - 50	875 - 900			
Bulgaria	< 5	30 - 40			
Croatia	< 5	100 - 120			
Czech Republic	5 - 10	100 - 120			
Denmark	5 - 10	130 - 140			
Estonia	5 - 10	40 - 50			
Finland	10 - 15	100 - 110			
France	175 - 200	2 200 - 2 300			
Germany	375 - 400	5 000 – 5 200			
Greece	25 - 30	600 - 620			
Ireland	5 - 10	15 - 20			
Italy	400 - 420	7 800 – 7 900			
Latvia	10 - 15	180 - 200			
Lithuania	< 5	330 - 350			
Luxembourg	5 - 10	40 - 50			
Netherlands	50 - 60	2 500 – 2 600			
Poland	15 - 20	900 - 950			
Portugal	5 - 10	50 - 70			
Romania	5 - 10	280 - 300			
Slovakia	< 5	120 - 140			
Slovenia	5 - 10	40 - 50			
Spain	35 - 40	750 - 780			
Sweden	5 - 10	130 - 150			
TOTAL	**1 300**	**24 000**			

Considering the REACH use description (ECHA, 2015), information currently available for this substance in the ECHA public dissemination website (ECHA, 2021a) is described next.

Formulation, transfer and repackaging of substances in preparations and mixtures

Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated

filling line, including weighing)

Formulation of adhesives and sealants

Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15: Use as laboratory reagent

Product category formulated:
- PC 1: Adhesives, sealants
- PC 0: Other: Construction products

Formulation of coatings or inks

Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent

Product category formulated:
- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay

Formulation - use as additive in plastic applications

Contributing activity/technique for the environment:

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- ERC2: Formulation into mixture

Contributing activity/technique for the workers:

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation and handling of substances bound in/on materials or articles
- PROC 24: High (mechanical) energy work-up of substances bound in/on materials and articles

Product category formulated:

- PC 32: Polymer preparations and compounds

Use as HTF at industrial sites

Contributing activity/technique for the environment:

- ERC7: Use of functional fluid at industrial site

Contributing activity/technique for the workers:

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities [EU REACH]
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent
- PROC 16: Use of fuels
- PROC28: Manual maintenance (cleaning and repair) of machinery

Product category used:

- PC 16: HTFs

Sector of end use:

- SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
- SU 9: Manufacture of fine chemicals
- SU 0: Other: various SUs

Laboratory analysis

Contributing activity/technique for the environment:

- ERC6b: Use of reactive processing aid at industrial site (no inclusion into or

onto article)
Contributing activity/technique for the workers:
- PROC 15: Use as laboratory reagent
Product category used:
- PC 21: Laboratory chemicals

Use of adhesives and sealants at industrial sites
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article
Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
Product category used:
- PC 1: Adhesives, sealants
Sector of end use:
- SU 0: Other: SU3

Direct use for industrial coatings or inks applications
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article
Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent
Product category used:
- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay
Sector of end use:
- SU 0: Other: SU3

Use as additive in plastic application
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers:
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Product category used:
- PC 32: Polymer preparations and compounds

Sector of end use:
- SU 12: Manufacture of plastics products, including compounding and conversion

Use as solvent or process medium
Contributing activity/technique for the environment:
- ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 16: Use of fuel

Sector of end use:
- SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
- SU 9: Manufacture of fine chemicals

Use as laboratory chemical by professionals
Contributing activity/technique for the environment:
- ERC9a: Widespread use of functional fluid (indoor)

Contributing activity/technique for the workers:

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- PROC 15: Use as laboratory reagent

Product category used:

- PC 21: Laboratory chemicals

Sector of end use:

- SU 0: Other: SU22

Use as HTF at professional sites[7]

Use of adhesives and sealants by professionals

Contributing activity/technique for the environment:

- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers:

- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
  PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 10: Roller application or brushing
- PROC 11: Non-industrial spraying
- PROC 13: Treatment of articles by dipping and pouring

Product category:

- PC 1: Adhesives, sealants

Sector of end use:

- SU 0: Other: SU22

Direct use for professional coatings or inks applications

Contributing activity/technique for the environment:

- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers:

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 11: Non-industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent
- PROC 28: Manual maintenance (cleaning and repair) of machinery

Product category used:

[7] In December 2022, the LR has analysed his database to determine at how many sites HTF is used in a professional setting. Thereby, it was determined that all sites receiving Terphenyl, hydrogenated as HTF are indeed industrial sites. Hence, the use of Terphenyl, hydrogenated as HTF at professional sites is no longer regarded as relevant.

- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay

Service life of articles produced from use as plasticiser
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of articles produced from use of coatings and inks
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of plastics
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Article Category:
- AC 13: Plastic Articles

Consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves
Contributing activity/technique for the environment:
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for consumers:
- AC 2a: Electrical/electronic articles covered by the Waste Electrical and Electronic Equipment (WEEE) Directive

In the past Terphenyl, hydrogenated was used in carbonless copy paper. Terphenyl, hydrogenated contaminants have been detected in food cardboard packages made from recycled material containing carbonless copy paper (Sturaro, A. et al, 1995). However, this use has been terminated many years ago. Via internet search of the Dossier Submitter, one "exotic"[8,9] application was found, Terphenyl, hydrogenated was used as evaporation modifier for insecticides in electric vaporizer against mosquitoes. This application seems to have stopped as well.

Annex E will describe in further detail the uses and applications and the impacts resulting from the restriction proposal by the Dossier Submitter.

[8] Microsoft Word - 00000000000000173798_1100764895210 (schneckenprofi.de)
[9] EPO - European publication server

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A.3. Uses advised against by the registrants

Consumer uses have been designated by the registrants as uses advised against according to the ECHA public dissemination website (ECHA, 2021a). Consumer uses on coating or ink applications and as adhesives and sealants are advised against.

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Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Name and other identifiers of the substance(s)

An overview of the name of the substance and other identifiers is given in **Table 7**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the Substance of Very High Concern (SVHC) Support Document (ECHA, 2018a) or the Chemical Safety Report (CSR) from the LR (Solutia, 2019).

Table 7. Substance identification information

Property	**Substance**
Regulatory process name	Terphenyl, hydrogenated Terphenyls, hydrogenated
IUPAC names	Hydrogenated Terphenyl Terphenyl, hydriert Terphenyl, hydrogenated
Other names (trade names and abbreviation)	Partially hydrogenated terphenyls PHT
EC number	262-967-7
EC name	Terphenyl, hydrogenated
CAS number	61788-32-7
CAS name	Terphenyl, hydrogenated
Molecular formula	$C_{18}H_n$ (n >18-36)
Molecular weight range	≥236 - ≤248

Type of substance:

Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Description of the UVCB substance:

Terphenyl, hydrogenated is produced by hydrogenation of a mixture of o-, m- and p-terphenyl and various quaterphenyls. The degree of hydrogenation is typically below 75%. Terphenyl, hydrogenated is a complex substance containing isomers of terphenyl and quaterphenyls as well as their hydrogenated versions.

Methods of manufacture of the UVCB substance Terphenyl, hydrogenated:

This UVCB substance is manufactured by the batchwise, partial catalytic hydrogenation of the complete mixture of the ortho-, meta- and para- isomers of terphenyl, with a lesser amount of quaterphenyl isomers. There is no physical blending of any of the constituents to make this UVCB substance. Commercially available hydrogenated terphenyls are approximately 40%

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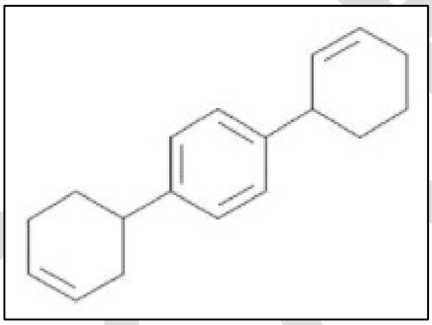
hydrogenated mixtures of ortho-, meta-, and para-terphenyls in various stages of hydrogenation, which are clear, yellow oils (Boogaard P.A., 2019).[10]

According to a patent (CN103804114A, 2014)[11], Terphenyl, hydrogenated is manufactured within the production process of biphenyl ($C_{12}H_{10}$, CAS 92-52-4). Basically, terphenyls are manufactured merely as an accompanying product in the manufacture of biphenyl and vice-versa. Consequently, the economical manufacturing of both substances separately is not possible on commercial scale. The Danish EPA published in its report on Biphenyl (40 - FINAL REPORT, 2014)[12], that Monsanto (now Solutia) is manufacturing biphenyl via the dehydrocondensation of benzene and production is carried out in gas or electrically heated tubular reactors at 700 – 800°C with residence and contact times of only a few seconds. The valuable accompanying substances produced are terphenyls, which come in the form of ortho-, meta-, para-, tri- and poly-terphenyl isomers. The yield is considered to be in the area of 50/50 between biphenyl and terphenyls (Thompson Q., 1992).

Origin:

Organic.

Structural formula:



B.1.2. Composition of the substance(s)

The composition of the substance includes fully aromatic structures such as terphenyls, quaterphenyls, pentaphenyls and structures resulting from the hydrogenation of these constituents such as 1-cyclohex-2-en-1-yl-4-cyclohex-3-en-1-ylbenzene.

According to the SVHC Support Document (ECHA, 2018a), representative structures from identified groups of constituents are shown in **Table 8**:

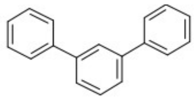
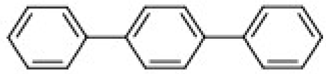
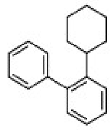
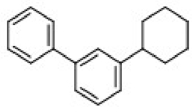
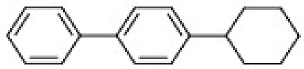
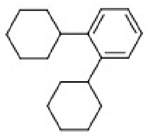
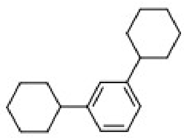
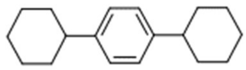
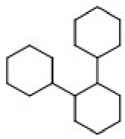
Table 8. Representative structures from identified groups of constituents

Group	Contains	Representative structure	
		Name (CAS)	Structure

[10] Boogaard P.J., Professor of Environmental Health and Human Biomonitoring, Wageningen University and Research Centre, and Toxicologist, Shell International BV, The Hague (until December 31, 2019). Hydrogenated terphenyl | Advisory report | The Health Council of the Netherlands

[11] CN103804114A - Method for preparing hydrogenated terphenyl - Google Patents

[12] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net) https://prodstoragehoeringspo.blob.core.windows.net/9cbcbe23-83c1-4ff5-92bc-183a263dfe86/40%20-%20FINAL%20REPORT%20-%20Biphenyl%20LOUS%20-%202014%2011%2004.pdf

o-T	ortho-terphenyl	1,2-terphenyl (CAS 84-15-1)	
m-T	meta-terphenyl	1,3-terphenyl	
p-T	para-terphenyl	1,4-terphenyl (CAS 92-94-4)	
o-HT1	1-ring hydrogenated terphenyls	2-cyclohexylbiphenyl	
m-HT1		3-cyclohexylbiphenyl	
p-HT1		4-cyclohexylbiphenyl	
o-HT2	2-ring hydrogenated terphenyl	1,2-dicyclohexylbenzene	
m-HT2		1,3-dicyclohexylbenzene	
p-HT2		1,4-dicyclohexylbenzene (CAS 1087-02-1)	
o-HT3	3-ring hydrogenated terphenyls	o-tercyclohexyl	

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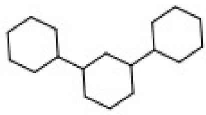
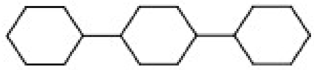
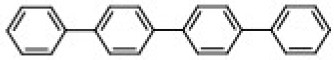
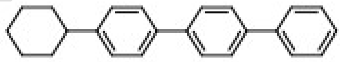
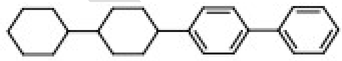
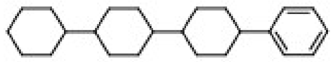
m-HT3		m-tercyclohexyl	
p-HT3		p-tercyclohexyl	
p-Q	Quaterphenyls	para-quaterpheny	
p-HQ1	1-ring hydrogenated quaterphenyls	4-cyclohexylterphenyl	
p-HQ2	2-ring hydrogenated quaterphenyls	dicyclohexylbiphenyl	
p-HQ3	3-ring hydrogenated quaterphenyls	tercyclohexylbenzene	

It is not possible to know the exact content of these constituents in the final Terphenyl, hydrogenated product, However, ortho-terphenyl (which is the constituent that fulfils both vP and vB criteria) occurs in significant concentrations in the UVCB substance (> 0.1%).

Although o-terphenyl is the component that categorises Terphenyl, hydrogenated as a vPvB substance, the restriction proposal applies to the UVCB substance as a whole for regulatory and compositional reasons.

Regarding the regulatory process, it is worth noting that both the Annex XV Dossier for identification of the substance as SVHC on the basis of the criteria set out in REACH Article 57 (Tukes, 2018), and the support document for identification of the substance as an SVHC because of its vPvB properties (ECHA, 2018a), concluded on the assessment of Terphenyl, hydrogenated as a UVCB substance and not on the assessment of their individual components. Literally, both documents state: "As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1 % w/w), terphenyl, hydrogenated is considered to fulfil the vPvB criteria. In conclusion, terphenyl, hydrogenated meets the criteria for a vPvB substance according to Article 57 (e) REACH".

Regarding the composition of Terphenyl, hydrogenated, o-terphenyl is part of the UVCB substance (as the other individual components) and cannot be considered in a separate way. O-terphenyl (CAS 84-15-1) is not a chemical product itself and it is not marketed as an individual substance in the EU. Furthermore, it has not been registered under REACH and, therefore, its individual restriction would not make sense.

The composition of the substance (boundary) according to the SDS[13] is the following:

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[13] THERMINOL-66-SDS-EASTMAN.pdf (americasinternational.com)

Table 9. Substance composition

Constituent	Reference name	Concentration range (w/w)	EC number	CAS number
1	Terphenyl, hydrogenated	74 - 87	262-967-7	61788-32-7
2	Terphenyl	3 - 8	247-477-3	26140-60-3
3	Quaterphenyls, Pentaphenyls and hexahydropentaphenyls, their isomers and other hydrocarbons	10 - 8	273-316-1	68956-74-1

B.1.3. Physicochemical properties

An overview of the physiochemical properties is given in **Table 10**. Unless otherwise stated, the data are taken from the REACH Registration on the ECHA public dissemination website (ECHA, 2021a), the SVHC Support Document (ECHA, 2018a) and the CSR of the LR (Solutia, 2019).

Table 10. Physicochemical properties

Property	Substance	Value	Reference
Physical state	Terphenyl, hydrogenated (CAS 61788-32-7)	Clear pale-yellow liquid	Lead Dossier
Melting point - Freezing point	Terphenyl, hydrogenated (CAS 61788-32-7)	below -24°C (pour point)	ECHA, 2018a
Boiling point	Terphenyl, hydrogenated (CAS 61788-32-7)	342-400°C (1013 hPa)	ECHA, 2018a
Density	Terphenyl, hydrogenated (CAS 61788-32-7)	1 013 (20°C)	ECHA, 2018a
Vapour pressure			
Partition coefficient	Terphenyl, hydrogenated (CAS 61788-32-7)	5.3 - 6.5 (20°C)	ECHA, 2018a
Water solubility	Terphenyl, hydrogenated (CAS 61788-32-7)	0.061 mg/L (20°C)	ECHA, 2018a
Flashpoint	Terphenyl, hydrogenated (CAS 61788-32-7)	170°C (1013 hPa)	ECHA, 2018a

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Auto flammability	Terphenyl, hydrogenated (CAS 61788-32-7)	374°C (1013 hPa)	Lead Dossier
	Terphenyl, hydrogenated (CAS 61788-32-7)	399°C (1013 hPa)	Lead Dossier
Viscosity	Terphenyl, hydrogenated (CAS 61788-32-7)	133 mm^2/s (static, 20°C)	Lead Dossier
	Terphenyl, hydrogenated (CAS 61788-32-7)	79.56 mm^2/s (25°C)	Lead Dossier Unnamed study report (1994)

B.2. Manufacture and uses (summary)

The data on manufacture and uses are described in **Annex A**: Manufacture and uses.

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Currently there is no harmonised classification for Terphenyl, hydrogenated included in Annex VI of the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

There is also no registered proposal on the Registry of Intention for harmonised classification and labelling (CLH).

B.3.2. Classification and labelling in classification and labelling inventory - Industry's self-classification(s) and labelling

<u>Classification and labelling (C&L) Inventory</u>

The range of classifications that have been notified to the C&L Inventory (ECHA, 2021c), alone or combined, is the following:

- Not classified
- Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects)
- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)
- Aquatic Chronic 4 (H413: May cause long lasting harmful effects to aquatic life)
- Aquatic Acute 1 (H400: Very toxic to aquatic life)

The status of the notifications in the C&L Inventory (ECHA, 2021c) checked on 12th October 2021 is the following:

- Number of aggregated notifications: 8
- Total number of notifiers: 669

Detailed notifications are given in **Table 11**.

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Table 11. C&L notifications

Aggregated Notification	Classification		Labelling		M-Factors	Additional Notified Information	Number of Notifiers	Joint Entries
	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Pictograms and Signal Word Code(s)				
1	Aquatic Chronic 2	H411	H411	GHS09		State or Form	27	X
2	Aquatic Chronic 4	H413	H413			State or Form	596	
3	Aquatic Chronic 2	H411	H411	GHS09			18	
4	Not classified						15	
5	Aquatic Chronic 4	H413	H413		M (Chronic) = 0	State or Form	7	
6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H410	GHS09 Wng		State or Form	3	
7	Aquatic Chronic 1	H410	H410	GHS09 Wng	M (Chronic) = 1		2	
8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	H400 H410	GHS09 GHS07 Wng			1	

<u>Self-classification by industry</u>

The co-registrants of Terphenyl, hydrogenated provided the following self-classification in the registration dossier (ECHA, 2021a):

- Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects)

The labelling information provided by the registrants in the registration dossier is the following:

- Hazard statement - code: Toxic to aquatic life with long lasting effects - H411
- Pictogram code: GHS09 (environment)

- Signal word code: no signal word
- Precautionary statement - code: Avoid release to the environment - P273
- Precautionary statement - code: Collect spillage - P391
- Precautionary statement - code: Dispose of contents/container to ... …in accordance with local/regional/national /international regulations (to be specified). Manufacturer/ supplier or the competent authority to specify whether disposal requirements apply to contents, container, or both - P501.

B.4. Environmental fate properties

The environmental fate properties have been summarised previously (ECHA, 2018a) and were the key arguments leading to the identification of Terphenyl, hydrogenated as an SVHC due to its vPvB properties based on a weight of evidence approach of the available data.

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From the available data it can be definitively concluded that at least o-terphenyl fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), Terphenyl, hydrogenated is considered to fulfil the vPvB criteria. In conclusion, Terphenyl, hydrogenated meets the criteria to be considered a vPvB substance according to Article 57 (e) of REACH.

The following sub-sections on the environmental fate properties of the substance are therefore just summarizing the full data set for Terphenyl, hydrogenated.

B.4.1. Degradation

Biodegradability in water

Several tests have been conducted to assess the biodegradability of hydrogenated Terphenyls. Most of the studies were carried out with hydrogenated Terphenyls as test substance; however, a limited number of study reports are also available for dilutions of the test substance. Whereas the primary test substance contains 40% of hydrogenated Terphenyls, two other test substances consist of 30% hydrogenated Terphenyls and a 40% hydrogenated polyphenyl mixture, respectively.

With the primary test substance different types of biodegradation tests were carried out. Reports of ready biodegradability tests monitoring CO_2 evolution (% of CO_2 produced compared to theoretical CO_2 production) yielded the following results after 35 days: 1% (initial substance concentration 15.1 mg/L) and 3% (initial substance concentration 10.3 mg/L) in the first test, while 3% at starting concentration of 45.8 mg/L in the second test (Saeger et al., 1977). After acclimation of the inoculum in the first test 50% degradation was observed (initial test concentration 16.7 mg/L) after 46 days.

Several reports of inherent biodegradability tests (semi-continuous activated sludge tests - SCAS) with different feed levels, test durations and exposure durations of the inoculum are available. 68.1% primary degradation was observed in 24 hours in a first test (Saeger et al., 1972), whereas an overall disappearance rate of 35.1 ± 8.6% using a 24-hour cycle (overall value calculated over four measurement periods in a testing period of nine months) was calculated in another test (Saeger and Tucker, 1970). With extended exposure of the residue after the normal test period to the activated sludge, nearly complete disappearance was achieved. This observation was confirmed by another SCAS test (Monsanto report AC-71-SS-4, 1970), which indicated that a primary biodegradation rate of 49 ± 7% (using a 24-hour cycle) could be obtained with non-acclimated activated sludge during the latter stage of the test, while significantly lower rates were obtained during the first 12 weeks of the test. In yet another SCAS test an overall primary degradation rate of 64 ± 5% using a 24-hour cycle was observed when using an acclimated inoculum (Saeger et al., 1977). The results clearly indicated the benefits of an extended acclimation period. Furthermore, it was noted that although differences exist in the degradation rate of the various constituents of the test substance, no evidence was found of highly resistant constituents. Finally, a river die away test with the primary test substance showed that 80% of the test substance had disappeared after 50 days when starting at a 1 ppm level (Monsanto report AC-71-SS-4, 1970).

Tests with the two other test substances yielded results that corresponded to expectations based on the composition of the different substances: since the level of hydrogenation is lower than 30% hydrogenated Terphenyls, the substance contains a higher proportion of constituents containing only one hydrogenated ring. The latter are considered to be more biodegradable compared to Terphenyl constituents with two hydrogenated rings. Conversely, the test substance with 40% hydrogenated polyphenyls has a higher degree of hydrogenation and is therefore expected to be less biodegradable.

A river die-away test with 30% hydrogenated Terphenyls showed that after 14 days the initial level of test substance was reduced by 95% (Gagel et al., 1983). After 28 days no constituents of the substance could be detected anymore. In addition, a SCAS test with this substance yielded mean disappearance rates of 68.1 ± 6.5 (95% confidence interval) and 65.6 ± 13.3

(95% confidence interval) at addition rates of 5 and 20 mg per 24h cycle, respectively (Saeger et al., 1972). After 4 weeks, no constituents of the test substance were detected anymore.

Finally, a ready biodegradability test with the test substance with 40% hydrogenated polyphenyls (with initial concentration of 20.9 mg/L) gave a mean value of 14% CO^2 evolution, indicating a low extent of mineralization (Monsanto report ES-80SS-34).

To conclude, it can be stated that the primary test substance with 40% hydrogenated Terphenyls is moderately biodegradable provided that sufficient time for acclimation of the inoculum is provided. Moreover, differences in degradation rates of the various constituents have been observed. However, there is no evidence of highly resistant constituents. Test results with other substances such containing 30% hydrogenated Terphenyls or 40% hydrogenated polyphenyls respectively moreover indicated that the extent of biodegradability is related to the level of hydrogenation.

Biodegradability in soil

The degradation rate (DT50 and DT90) was determined of 14C-labelled 1,4-dicyclohexy-lbenzene in three different soils (Speyer 2.2 (loam), Speyer 2.3 (sandy loam) and Speyer 6S (clay)) and its degradation route in one of these soils (Tan, 2009). For this purpose, (phenyl-14C(U))-p-dicyclohexylbenzene was incubated in three soils in the dark. The concentration of the substance was determined after various incubation periods by HPLC of the soil extracts. Major metabolites were characterized and identified if feasible. The duration of the incubation was 120 days.

The extractable activity decreased during the first 14 days of incubation from 99% of the applied radioactivity to approximately 25 to 50.3%. In all investigated soils, the soil extractable activity gradually decreased to 8.1 – 10.5% at the end of the incubation.

Phenyl-14C(U))-p-dicyclohexylbenzene quickly degraded and mineralized in the tested soils. In Speyer 6S soil three major metabolites were formed that were above 10% of the applied activity. In Speyer 2.3 two metabolites were twice above 5% of the applied radioactivity at two consecutive time points. The major metabolites degraded rapidly. Other metabolites were only formed in minor amounts.

The DT50 (d) for the parent compound was 4.1, 4.6 and 1.8 in Speyer 2.2, Speyer 2.3, and Speyer 6S, respectively.

B.4.2. Environmental distribution

The Koc and log Koc values of the main peak of the test substance were 3.0 x 10e+05 and 5.5 (Baltussen E., 2010). The Koc and log Koc values of additional peaks of the test substance ranged from 1.8 x 10e+04 - 1.2 x 10e+06 and from 4.2 to 6.1.

B.4.3. Bioaccumulation

The information included in this Section is mainly extracted from IUCLID data set (ECHA, 2021a).

For the assessment of the bioaccumulative or bioconcentration potential three studies were available, one of which clearly presented the most complete, reliable, and relevant data. In this study, bluegill fish (Lepomis macrochirus) were exposed to a mean concentration of 32 µg/L of the mixture of Terphenyl, hydrogenated, partially hydrogenated quater- and polyphenyls, and Terphenyl in a flow through system for 42 days, after which a depuration phase of 42 days took place (Heidolph et al., 1983). The bioconcentration factors for the mixture of Terphenyl, hydrogenated, partially hydrogenated quater- and polyphenyls, and Terphenyl (whole substance) calculated for whole fish and muscle tissue were 2 000 (3 000 Biofac) and 700 (1 300 Biofac), respectively. The uptake and depuration rate constants, T1/2,

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and time to equilibrium for whole fish were calculated by the Biofac model to be 192 L/kg/day, 0.06 days 1 ,11 days and 3 days, respectively.

It should be noted though that the relevance of this study is mainly situated in the results of the responses of group I (representing probably o-Terphenyl and some Terphenyl with one ring saturated) and group II (mixture of Terphenyls with one and two rings saturated). For group I, the mean exposure concentration was 1.5 µg/L and the calculated bioconcentration BCFs were 5 200 (9 100 Biofac) and 2 000 (3 100 Biofac) for whole fish and muscle tissue, respectively. For group II the mean exposure concentration was 19 µg/L and the calculated BCFs for whole fish and muscle tissue were 2 400 (3 700 Biofac) and 800 (1 200 Biofac), respectively.

Aim of a further key study (Schlechtriem et al., 2017) was to evaluate the use of column-generated analyte concentrations (CGACs) for fish BCF studies with hydrophobic organic chemicals (HOCs). The test followed basic parameters of guideline 305 of the Organisation for Economic Co-operation and Development (OECD). A solid-phase desorption dosing system was developed to generate stable concentrations of HOCs without using solubilizing agents. In the flow-through tanks a continuous flow of approximately 22 L/h (first study) or 21 L/h (second study) was maintained throughout the test, equivalent to 7.5 volume replacement and 7.2 volume replacement, respectively, per day. In both studies, the test groups were exposed for 56 days (uptake period) and then transferred into a new aquarium where the fish were kept in clean water (depuration period), which was constantly replaced at the same rate as the previously applied test medium. The depuration periods were 28 days and 56 days during the first and second BCF studies, respectively. A kinetic BCF of 12 040 (L/kg wet wt) was determined for o-Terphenyl, indicating the bioaccumulation potential of the compound. The tested solid-phase desorption dosing system is suitable to provide stable aqueous concentrations of HOCs required to determine BCF in fish and represents a viable alternative to the use of solubilizing agents for the preparation of test solutions.

The available supporting study MITI of 2004 (the full reference is not available) was also indicative of the bioaccumulative potential of the substance. This is however currently a K4 study since the original study report is not available (MITI, 2004).

B.4.4. Secondary poisoning

The hazard assessment conclusion for secondary poisoning (PNEC oral) is 2.22 mg/kg food.

B.5. Human health hazard assessment

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.6. Human health hazard assessment of physicochemical properties

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.7. Environmental hazard assessment

B.7.1. Aquatic compartment (including sediments)

The information provided is based on those studies and pieces of information, relevant for risk assessment purposes (ECHA, 2021a). More specifically, this information is considered relevant for classification and labelling purposes of the substance and PNEC derivation. Additional studies were included in the IUCLID data set for PBT purposes. However, these studies are not dealt with in detail for the purpose of the restriction proposal, because the chemical is a vPvB substance.

Summary on aquatic toxicity:

Aquatic toxicity related to hydrogenated terphenyls has been assessed both in acute and chronic toxicity tests. These tests however cover different trophic levels (fish, invertebrate, algae) and among the fish and invertebrates, different species were used.

Fish

From the fish tests (all acute 96h tests) it was concluded that the substance is not acutely toxic towards fish at concentrations well above the water solubility (Griffin, 1979; Thompson, 1979; Rice, 1972; Adams 1979; BTL, 1972). In four out of five tests, the LC50 (96h) was reported to be > 1 000 mg/L test substance. The fifth test yielded a 10 ppm < LC50 (96h) < 100 ppm. It should be noted however that this fifth test was the only one that was not carried out with the primary test substance with 40% hydrogenated terphenyls, but with a substance containing 30% hydrogenated terphenyls, which thereby has a slightly different composition compared to the primary test substance (BTL, 1972).

Invertebrates

The acute toxicity towards aquatic invertebrates for the primary test substance was evaluated for multiple species: Daphnia magna, Mysidopsis bahia, Gammarus fasciatus, and Paratanytarsus parthenogenetica. Based on the results reported in all these studies, no toxicity was observed up to water solubility levels (approximately 0.06 mg/L).

The most recently performed study was the only study reporting measured exposure concentrations (Powell and Moser, 1996). This limit test with Terphenyl, hydrogenated indicated that the EC50 (48h) is > 1.34 mg/L (measured concentration). It should be noted however that a dispersant was used to dissolve the test substance. The other EC50 (48h) values for freshwater invertebrates reported for Terphenyl, hydrogenated ranged from 0.1 mg/L to > 1.5 mg/L, all based on nominal concentrations in the presence of a solvent (Forbis, 1979; Powel and Moser, 1996; Adams, 1979; Gledhill, 1984; Hoberg, 1984a and 1984b). Additional tests performed with a "read-across" substance (substance containing 40% hydrogenated polyphenyls) on Daphnia magna and Chironomus tentans, generally indicated a higher toxicity of this substance with EC50 48h values ranging from 0.011 to 0.52 mg/L (Renaudette and Adams, 1984; Monsanto, 1980; Calvert et al., 1982). However, due to the difference in chemical composition of the substance (which contains a larger fraction of hydrogenated quaterphenyls in comparison to the primary test substance), these values were not taken into account further in the risk assessment. To conclude, although the lowest EC50 (48h) is 0.1 mg/L, the test reporting an EC50 (48h) > 1.34 mg/L is considered the most relevant and reliable study. For risk assessment purposes this result is taken into account.

The determined chronic toxicity towards aquatic invertebrates is based on the 21 days reproduction study performed with Daphnia magna on Water Accommodated Fractions of 1 and 5 mg/L Terphenyl, hydrogenated (Tobor-Kaplon M.A., 2014). This test resulted in a No Observed Effect Loading Rate (NOELR) for reproduction < 1 mg/L, a NOELR for mortality of 1 mg/L and a NOELR for growth < 1 mg/L. At the Loading Rate of 1 mg/L, a 32% reduction of the reproduction was observed. As the test design did not include lower concentrations, this due to technical reasons, no exact NOELR could be determined.

Algae

Two phytotoxicity studies (K1 & K2) are available, evaluating the effect of hydrogenated terphenyls on the freshwater alga Selenastrum capricornutum (new name is Pseudokirchneriella subcapitata) (Hollister, 1979; Weltens, 2010). In the oldest study (K2), only nominal concentrations were reported (10, 32, 56, 100 and 320 mg/L). The basis of the reported effects was in vivo chlorophyll a (for all time points) and cell numbers (96h). Based on the decrease of in vivo chlorophyll a, the calculated 96-hour EC50 was 44 ppm (95% CL 1 - 1586 ppm). The calculated 96-hour EC50 based on cell number decrease was 56 ppm (CL 95% of 4 -743 ppm). In the most recent study (K1), algae were exposed to water soluble fractions of hydrogenated terphenyls. The presence of Terphenyl, hydrogenated in these WAFs could be measured with HPLC when solutions were freshly prepared. This soluble fraction however disappeared during the exposure time both in filtered and unfiltered WAFs and it was not clear from the results how fast the test substance disappears. The initial presence of these soluble compounds in the WAFs however does not interfere with normal algal growth rate for WAFs produced with nominal concentrations up to 100 mg/L Terphenyl, hydrogenated. As no effects were seen in the test range, no effect values could be defined either.

Conclusion

Based on the available data, it can be concluded that invertebrates (more specifically Daphnia magna) are the most sensitive species. As both acute and long-term toxicity information is available covering that species there is no need to collect more ecotoxicology related information on other (vertebrate) organisms.

B.7.2. Terrestrial compartment

No relevant and reliable information is available for the terrestrial compartment.

B.7.3. Atmospheric compartment

No relevant and reliable information is available for the atmospheric compartment.

B.7.4. Microbiological activity in sewage treatment systems

According to Column 2 of Annex IX and X of REACH, toxicity testing in soil microorganisms shall be proposed if the chemical safety assessment indicates the need to further assess the effects on soil organisms. Based on the currently available dataset, the EPM calculated PNEC values for the soil compartment, and the risk assessment, there is no need to propose any further testing on soil organisms. RCR values are all below 1 (Solutia, 2019).

B.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

No relevant and reliable information is available for the food chain (secondary poisoning).

B.8. PBT and vPvB assessment

B.8.1. Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Terphenyl, hydrogenated is a very persistent and very bioaccumulative (vPvB) substance according to article 57 (e) of Regulation (EC) No 1907/2006 (REACH). The ECHA Member States Committee included the substance on the list of Substances of Very High Concern on

27.06.2018. See as well **Annex B.4.1.** on Degradation and **Annex B.4.3** on Bioaccumulation for more information.

Further details as the basis for these conclusions are available in the corresponding decision of the ECHA MSC[14] and support documents (ECHA, 2018a) available on the ECHA Website. Readers are referred directly to these documents for additional information. Furthermore, detailed information is provided in Section 8 to the CSR of the LR (Solutia, 2019).

The UVCB substance was assessed by evaluating the different relevant constituents present in the substance. The P, vP, B, and vB behaviours of some of the constituents defined in **Table 8** are detailed in **Table 12.**:

Table 12. P/vP and B/vB conclusions of selected constituents of Terphenyl, hydrogenated

Group	Contains	Name (CAS)	Persistence	Bioaccumulation
o-T	ortho-terphenyl	1,2-terphenyl (CAS 84-15-1)	P and vP	B and vB
m-T	meta-terphenyl	1,3-terphenyl	Potentially P or vP	Not possible to conclude
p-T	para-terphenyl	1,4-terphenyl (CAS 92-94-4)	P and vP	Potentially B and vB
p-HT1	1-ring hydrogenated terphenyl	4-cyclohexylbiphenyl	Potentially P or vP	B and vB
p-HT2	2-ring hydrogenated terphenyl	1,4-dicyclohexylbenzene (CAS 1087-02-1)	Potentially P or vP	B and vB
p-HT3	3-ring hydrogenated terphenyls	p-tercyclohexyl	Potentially P or vP	Potentially B
p-Q	Quaterphenyls	para-quaterpheny	P and vP	B
p-HQ1	1-ring hydrogenated quaterphenyls	4-cyclohexylterphenyl	Potentially P or vP	Potentially B and vB
p-HQ2	2-ring hydrogenated quaterphenyls	dicyclohexylbiphenyl	Potentially P or vP	Potentially B and vB
p-HQ3	3-ring hydrogenated quaterphenyls	tercyclohexylbenzene	Potentially P or vP	Potentially B and vB

At least o-terphenyl fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1%), the UVCB substance Terphenyl, hydrogenated is considered to fulfil vPvB criteria.

Justification of vPvB classification for o-terphenyl

[14] https://echa-term.echa.europa.eu/web/guest/candidate-list-table/-/dislist/details/0b0236e18250183f

For ortho-terphenyl and meta-terphenyl, the potential for primary and ultimate degradation is demonstrated in studies on ortho-terphenyl. According to the approach of the study authors the half-life for disappearance of parent substance is below the threshold for freshwater and the original calculations based on study results revealed very short dissipation half-lifes, demonstrating that the mixture as tested does not persist in soil. Based on recent evaluation results of the environmental Member State competent authority (Finland), the modelling approach chosen by the study authors was not appropriate to describe the degradation of the compound in soil. According to the outcome of remodelling of the study results by the Finnish competent authority, terphenyl fulfils the vP criterion in soil based on the degradation study. The different isomers of terphenyl, quaterphenyl, and polyphenyl were not differentiated in this study. Nevertheless, the reliability of this soil dissipation test is limited due to the fact that information on the composition of the tested mixture is missing. In general, the Finnish competent authority considers that degradation of a hydrocarbon in a mixture study may be overestimated compared to testing of each constituent separately (due to co-metabolism).

However, in the present case the possible overestimation is acceptable as the half-life for terphenyl fulfils the vP criterion.

B.8.2. Emission Characterisation

The objective of an emission characterisation is to identify and estimate the amount of the releases of a PBT or vPvB-substance to the environment; and to identify exposure routes by which humans and the environment are exposed to a PBT or vPvB-substance. Further information on potential emissions and exposure is provided under Section B.9. Exposure Assessment.

B.9. Exposure assessment

According to registration information, Terphenyl, hydrogenated is not manufactured within the EU after Brexit. It is mainly used as HTF within closed systems at industrial sites. Also related to the HTF uses is the industrial "use in laboratory analysis" where small amounts of in-use HTF is analysed to determine its lifetime. The use of this substance as a plasticiser is the second relevant use. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. Terphenyl, hydrogenated is used as a plasticiser mainly for the production of sealants and adhesives. The final sealants/adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables). This application is addressed in the "additive in plastic application" scenarios as well as the corresponding "Plastic articles" service life scenario. Moreover, Terphenyl, hydrogenated is also used as plasticiser in coatings and inks. In addition, professional service life scenarios are also relevant for Terphenyl, hydrogenated since the substance is incorporated into/onto articles when used in adhesives/sealants as well as in coatings/inks.

Furthermore, Terphenyl, hydrogenated is also used as solvent or process medium by the industry and as laboratory chemical (e.g., as microscope immersion oils) by professionals.

In addition, a general scenario ("Formulation, transfer and repackaging of substances in preparations and mixtures") related to the formulation life cycle stage was indicated as relevant for Terphenyl, hydrogenated. Since specific formulation scenarios are also indicated ("Formulation of adhesives and sealants", "Formulation of coatings/inks" and "Formulation - use as additive in plastic applications") the general formulation will herein solely be used to cover formulation of laboratory chemicals used by professionals.

Moreover, the SCIP database was screened for Terphenyl, hydrogenated. At the date of access (2 March 2022) well over 12 000 articles containing Terphenyl, hydrogenated are included in the SCIP database. Most of them relate to polymers as well as rubber and elastomers (in sum > 60%). Moreover, the number of sealants containing Terphenyl, hydrogenated is quite high

(> 25%). Some further articles such as inks and sensors (e.g., in ovens) are also found. The total number of entries in these cases was significantly lower. The information obtained through analysis of the SCIP database will be addressed in the exposure assessment (please refer to **Annex B.9.**).

Exposure of Terphenyl, hydrogenated mainly occurs from releases to air and water from point sources as well as via diffuse emissions. After emission to the environment the substance is distributed by various processes such as deposition from air to soil/water bodies and adsorption to sludge in the sewage treatment plant (STP).

During the data collection phase of this proposal in summer 2021 via a Socio-Economic Assessment (SEA) Questionnaire to downstream users (see **Annex E**: Impact Assessment), the Dossier Submitter did ask as well on assessment of relevant emissions. The responses (obtained only from HTF users) have been reported collectively as negligible.

Currently there are six active registrations for Terphenyl, hydrogenated in the EU (see also **Annex A** and **Annex B.9.2.** for further information).

Up until now only a few international measurements of Terphenyl, hydrogenated in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with Terphenyl, hydrogenated, while Sturaro et al. (1995) detected Terphenyl, hydrogenated as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by the Norwegian Institute for Air Research (NILU) and the Norwegian Institute for Water Research (NIVA) (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including Terphenyl, hydrogenated.

Due to the vPvB property of Terphenyl, hydrogenated, emissions will lead to an increased exposure of humans and the environment since the substance will build up over time. Measures to reduce the ongoing emissions are therefore regarded as mandatory.

Currently, Terphenyl, hydrogenated is used in the following applications:

- Use in adhesives and sealants.
- Use in coatings and inks.
- Use as additive in plastic applications.
- Use as HTF systems.
- Use as HTF in thermostats in electromechanical temperature controls
- Use as solvent/process medium.
- Use as laboratory chemical.

The following exposure assessment considering these six main areas of use from all relevant life cycle stages includes:

- Formulation.
- Industrial use.
- Professional use.
- Release over the service life of articles.
- Release from waste.

"Manufacture" is also indicated on the ECHA's dissemination website as a relevant exposure scenario for Terphenyl, hydrogenated. As of today, only the LR is manufacturing Terphenyl, hydrogenated at the plant in Newport (UK). However, since the UK left the EU on 31 of January 2020, the manufacture conducted by the LR is no longer taking place within the EU. Since no other registrants manufacture Terphenyl, hydrogenated within the EU, it is not necessary to address the manufacture life cycle stage in the context of this restriction proposal.

The substance is registered in the EU under the REACH Regulation and, only limited information on the releases to the environment is available from the disseminated information on ECHA's webpage. In addition, specific information on the Identified Uses (IU) of the substance as well as its exposure patterns are obtained in a survey conducted in 2019 by the LR. Thereby, an advanced Exposure & Release Questionnaire was sent out to users as well as distributors. In this questionnaire, exposure related information on human health and the environment was requested. General information such as technical functions of the substance, total tonnages, relevant life-cycle steps and their respective use descriptors (Environmental Release Categories (ERCs), Process Categories (PROCs), Sectors of Use (SUs), and Product Categories (PCs)) was obtained, as well as process specific data on the IU. This included the identification of specific contributing scenarios incl. their Operational Conditions (OCs) and applied Risk Management Measures (RMMs). The Exposure & Release Questionnaire is attached in Appendix 1.

In total, more than 50 companies were contacted. Overall, 17 companies from different industry sectors provided a completed questionnaire. Hence, this extensive feedback has been evaluated and used for the following exposure and risk assessment. If no specific information was available, worst-case release estimates for the relevant scenarios are used.

- Formulation. Releases to the environment can occur from formulation of adhesives and sealants and coatings and inks. Information regarding the routes of release for sealants and adhesives is taken from FEICA / EFCC SPERC 2.1a.v3. For the coatings and inks CEPE SpERC 2.1c.v2 is applicable.

  Additionally a generic formulation scenario is indicated on ECHA's dissemination page to cover general formation, transfer and repackaging of the substance. A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. The formulation, transfer and repacking of Terphenyl, hydrogenated used as solvent/process medium by the industry or as laboratory chemical by professional is covered by this formulation scenario. No specific information on the releases to the environment is available.

  Moreover a generic formulation scenario the "Formulation - use as additive in plastic applications" is found on ECHA's webpage. Although this use is also listed in this report it is not assessed since it is already sufficiently covered by the following uses: "Formulation of coatings/inks" as well as "Formulation of adhesives and sealants". Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

  If Terphenyl, hydrogenated is used as HTF it is used as such. Formulation activities also including repacking are not relevant for the main use of Terphenyl, hydrogenated as HTF.

- Industrial use. Releases to the environment can occur from various industrial uses: the use as HTF, laboratory analysis of HTF samples, adhesives/sealants, coatings/inks, and as solvent/process medium. For the use as HTF and the laboratory analysis of HTF samples information is taken from the Exposure & Release Questionnaire. For the adhesives/sealants, the coatings/inks use and the use as solvent/process medium FEICA SPERC 5.1a.v3, CEPE SPERC 5.1a.v2 and ESVOC SPERC 4.1.v2, respectively, were used.
  Professional use. Releases to the environment can occur from various professional uses: the use as adhesives/sealants, coatings/inks and as laboratory chemical. For the adhesives/sealants and the coatings/inks use FEICA / EFCC SPERC 8f.1a.v2 and CEPE SPERC 8f.3a.v2, respectively, were used. For the use as laboratory chemical by professional no refinement was possible since no suitable information is available. In December 2022, the LR has analysed his database to determine at how many sites

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HTF is used in a professional setting. Thereby, it was determined that all sites receiving Terphenyl, hydrogenated as HTF are indeed industrial sites. Hence, the use of Terphenyl, hydrogenated as HTF at professional sites is no longer regarded as relevant.

- Article service life. Releases to the environment are likely to occur from long-life materials with low release, e.g., plastic articles such as cables or coatings/sealants used by the aerospace industry. Releases could occur during indoor as well as outdoor use of articles. No public information is available and only limited information is provided in the Exposure & Release Questionnaire (2018).

Below all IU including ERCs and PROCs, as listed on ECHA's dissemination page of the Terphenyl, hydrogenated dossier, are indicated.

The ERC describes the activity from the environmental (release) perspective. The PROC describes the tasks, application techniques or process types defined from the occupational perspective, including use and processing of articles by workers.

Hence, ERCs describe the process from which releases to the environment could occur and PROCs describe the processes from which occupational exposure could occur.

Formulation, transfer and repackaging of substances in preparations and mixtures

Contributing activity/technique for the environment:

- ERC2: Formulation into mixture

Contributing activity/technique for the workers:

- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Formulation of adhesives and sealants

Contributing activity/technique for the environment :

- ERC2: Formulation into mixture

Contributing activity/technique for the workers :

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15: Use as laboratory reagent

Formulation of coatings/inks
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent

Formulation - use as additive in plastic applications
Contributing activity/technique for the environment:
- ERC2: Formulation into mixture

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation and handling of substances bound in/on materials or articles
- PROC 24: High (mechanical) energy work-up of substances bound in /on materials and articles

Use as HTF at industrial sites
Contributing activity/technique for the environment:
- ERC7: Use of functional fluid at industrial site

Contributing activity/technique for the workers:
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch

processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities [EU REACH]
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 15: Use as laboratory reagent
- PROC 16: Use of fuels
- PROC28: Manual maintenance (cleaning and repair) of machinery

Laboratory analysis
Contributing activity/technique for the environment :
- ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers :
- PROC 15: Use as laboratory reagent

Use of adhesives and sealants at industrial sites
Contributing activity/technique for the environment:
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 13 : Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation

Direct use for industrial coatings/inks applications
Contributing activity/technique for the environment :
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 7: Industrial spraying
- PROC 8b: Transfer of substance or mixture (charging and discharging) at

dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent

Use as additive in plastic application
Contributing activity/technique for the environment :
- ERC5: Use at industrial site leading to inclusion into/onto article

Contributing activity/technique for the workers :
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 6: Calendaring operations
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Use as solvent/process medium
Contributing activity/technique for the environment :
- ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 16: Use of fuel

Use as laboratory chemical by professionals
Contributing activity/technique for the environment :
- ERC9a: Widespread use of functional fluid (indoor)

Contributing activity/technique for the workers :
- PROC 15: Use as laboratory reagent

Use as HTF at professional sites

In December 2022, the LR has analysed his database to determine at how many sites HTF is used in a professional setting.

Thereby, it was determined that all sites receiving Terphenyl, hydrogenated as HTF are indeed industrial sites. Hence, the use of Terphenyl, hydrogenated as HTF at professional sites is no longer regarded as relevant.

Use of adhesives and sealants by professionals
Contributing activity/technique for the environment :
- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers :
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring

Direct use for professional coatings/inks applications
Contributing activity/technique for the environment :
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Contributing activity/technique for the workers :
- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
- PROC 4: Chemical production where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes
- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities [EU REACH]
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 15: Use as laboratory reagent
- PROC 28: Manual maintenance (cleaning and repair) of machinery

Service life of articles produced from use as plasticiser
Contributing activity/technique for the environment:
- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:
- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of articles produced from use of coatings and inks
Contributing activity/technique for the environment:

- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:

- PROC 21: Low energy manipulation of substances bound in materials and articles

Service life of plastics

Contributing activity/technique for the environment:

- ERC10a: Widespread use of articles with low release (outdoor)
- ERC11a: Widespread use of articles with low release (indoor)

Contributing activity/technique for the workers:

- PROC 21: Low energy manipulation of substances bound in materials and articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and articles

Consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves

Contributing activity/technique for the environment:

- *not applicable*

Contributing activity/technique for consumers:

- AC2a: Electrical/electronic articles covered by the Waste Electrical and Electronic Equipment (WEEE) directive

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16.

In case other information on the releases are available and applicable for Terphenyl, hydrogenated, e.g., Specific Environmental Release Categories (SpERCs) or OECD Emission Scenario Documents this information is used in preference to the default release factors as indicated in ECHA Guidance R.16. Additionally, specific information was made available through the Exposure & Release Questionnaire (2018) by the LR.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any RMM that is used during the process.

Using more specific information (if available) instead of the default release factors guarantees a more realistic exposure assessment which is based on actual emissions.

However, since no other information was available the default release factors as indicated in ECHA Guidance R.16 (ECHA, 2016) had to be used. In the **Table 13** below, the default release factors for the relevant ERCs are indicated.

Table 13. Default release factors for the relevant ERCs

ERC	ERC description	Default release factor to air	Default release factor to water	Default release factor to soil
2	Formulation into mixture	2.5%	2%	0.01%
4	Use of non-reactive processing aid at industrial site (no inclusion into or onto article)	100%	100%	5%
5	Use at industrial site leading to inclusion into/onto article	50%	50%	1%
6b	Use of reactive processing aid at industrial site (no inclusion into or onto article)	0.1%	5%	0.025%

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ERC	ERC description	Default release factor to air	Default release factor to water	Default release factor to soil
7	Use of functional fluid at industrial site	5%	5%	5%
8c	Widespread use leading to inclusion into/onto article (indoor)	15%	30%*	n.a.
8f	Widespread use leading to inclusion into/onto article (outdoor)	15%	5%	0.5%
9a	Widespread use of functional fluid (indoor)	5%	5%	n.a.
9b	Widespread use of functional fluid (outdoor)	5%	5%	5%
10a	Widespread use of articles with low release (outdoor)	0.05%	3.2%	3.2%
11a	Widespread use of articles with low release (indoor)	0.05%	0.05%	n.a.

* The default release factor of 30% applies to activities/processes where the substance is dissolved/dispersed in a surplus of water and applied to an article via dipping/immersion or spreading (e.g. textile dyeing/finishing or application of polishes with floor cleaning water). For other widespread uses (e.g. use of paints and adhesives, including water based products) the release factor of 5% is applicable.

As indicated before, using the default release factors has to be regarded as worst-case approach overestimating the actual emissions (further referred to as "upper estimate"). For most of the IU it was possible to refine the exposure assessment using applicable SpERCs, OECD Emission Scenario Document and specific information made available through the Exposure & Release Questionnaire (2018). For further information refer to the respective scenario. The estimates of the refined assessment are referred to as "lower estimate". They are assumed to represent the reasonable worst-case emissions.

It is to be noticed that the number of articles containing Terphenyl, hydrogenated imported into the EU and exported from the EU is not known with any certainty. Hence, the exposure assessment for the service life scenarios is based on the volume of Terphenyl, hydrogenated itself supplied to the EU market. However, the total volume used for the exposure assessment (7 471 tonnes per year) is regarded as a worst-case estimate. Hence it is assumed that Terphenyl, hydrogenated in imported articles is sufficiently covered.

For the exposure assessment the total volume is derived by summarising the imported volumes reported by the registrants or using the upper limit of the tonnage band of a registration. In accordance with ECHA Guidance R.16, Figure R.16-8 the daily and annual use amount at a site is derived based on the tonnage per use per year, i.e., market tonnage. For Terphenyl, hydrogenated the total marketed tonnage is the volume imported into the EU. The volumes per use in the EU were split based on information provided by stakeholders (please refer to Chapter A.2 for further information). Hence, this is the ultimate basis for all uses except the HFT uses. To estimate the exposure associated with the use as HTF at industrial sites the assessment is conducted based the installed volumes instead of the imported volume used as HTF. Thereby, for the industrial use as HTF the highest used tonnage at the largest plant in the EU is used: 1 200 tpa. For the assessment of the "Use as HTF at industrial sites" the annual as well as the daily use amount at site is set to 1 200 tonnes.

For each of the exposure scenarios the used parameters are indicated in the following sections. Due to the fact that ranges are used (e.g., for the releases) a lower and upper range is also reported for the exposure estimates.

The properties of Terphenyl, hydrogenated that have been assumed in the exposure assessment were taken from ECHA's dissemination page (ECHA, 2021a) and the SVHC Support Document (ECHA, 2018a). A summary of the physico-chemical and fate properties is given in the table below (**Table 14**).

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Table 14. Properties of Terphenyl, hydrogenated used in the exposure assessment

Substance property	**Value**
Molecular weight	236 - 248
Molecular weight used for the assessment	248
Melting point at 101 325 Pa	-24°C
Vapour pressure	0.002 hPa at 20°C
Partition coefficient (Log Kow)	6.5 at 20°C
Water solubility	0.061 mg/L at 20°C
Biodegradation in water: screening tests	inherently biodegradable
Half-life in soil	≥ 218 d
Bioaccumulation (BCF)	5.2E3
Adsorption/Desorption: Koc at 20°C	3.16E5

The exposure assessment is presented in two parts for each exposure scenario. For each exposure scenario an overview table with the input parameters is given as well as a table displaying the initial releases to air, water and soil based on the release rates. The releases are calculated using generic exposure methods.

Uncertainties associated with this approach are discussed in Appendix F.

B.9.1. General discussion on releases and exposure

B.9.1.1. Summary of the existing legal requirements

Terphenyl, hydrogenated itself is currently not regulated by any legislation in the EU other than REACH. For this reason, other EU legislation related to PBT/vPvB substances is mentioned here.

The CLP Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, the classification 'hazardous for the aquatic environment' does include 'ready degradability' and 'potential to bioaccumulate' as criteria to consider, meaning that some aspects of persistence are taken into account.

The EU Water Framework Directive (Directive 2000/60/EC) provides a framework for the protection of inland surface waters, transitional waters, coastal water, and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as 'Priority Substances' (PS) and by requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges and losses of the PS and to phase out those deemed the most harmful ('Priority Hazardous Substances' - PHS). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC) for PS and PHS[15]. Member States must ensure that the EQS for the Priority Substances, are met in order to achieve 'good chemical status' in accordance with Water Framework Directive Article 4 and Annex V 1.4.3[16]. The PS list was replaced in 2013 via Directive 2013/39/EU, which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. Terphenyl, hydrogenated is not currently identified as a PS or PHS.

[15] http://ec.europa.eu/environment/water/water-dangersub/index.htm
[16] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0060-20141120

The Industrial Emissions Directive (2010/75/EU)[17] establishes the main principles for permitting and control of large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection. The manufacture and some uses of Terphenyl, hydrogenated are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents related to the use of Terphenyl, hydrogenated are available, the IED is considered of limited applicability for the risk management of Terphenyl, hydrogenated.

From an EU policy standpoint, the European Commission's (COM) new Circular Economy Action Plan announces initiatives along the entire life cycle of products. It targets their design and promotes circular economy processes to stimulate sustainable consumption. It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC) sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, and for improving efficient use of resources. An amendment[18] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA thus providing waste operators with information about hazardous substances in the waste they are processing.

B.9.1.2. Summary of the effectiveness of the implemented OCs and RMMs

According to the responses received to the 2021 SEA questionnaire (Appendix 4), when Terphenyl, hydrogenated is used as HTF, the substance is included in a closed system in which the potential releases to the environment can be considered negligible. Regarding RMMs, all of the respondents informed about the presence of different containment devices (e.g., collection vessels, retention systems in pumps and valves, etc.). In most cases, the system is designed with the piping lines fully welded, and only some specific items are flanged (as pumps or control valves). These flanged elements are specifically protected against leakages.

These RMMs are already considered during the design step of the system to guarantee its tightness, thinking on the applicable normative (as the Pressure Equipment Directive – PED[19]) and international standards (as DIN 4754-1).

Regarding OCs, HTF systems are usually managed by expert trained operators, and they are periodically inspected, internally or by external competent technical bodies. Furthermore, internal control tests (e.g., to check the suitability of joints) and programs (e.g., periodical surveillance of potential leakages) are in place. The most important controls are the Terphenyl, hydrogenated level monitoring, because it is the best tool to quickly identify any loss of substance volume from the closed system, and the analysis of the Terphenyl, hydrogenated quality (basically defined by the content of low boiling fraction), to guarantee an efficient work of the system.

Special operations, such as sampling, drain of the system, and replacement of the Terphenyl, hydrogenated, are performed following specific procedures to avoid the release of the substance. Most of the sites have calamity basins to control potential accidents during these processes. Also, there are specific procedures for the storage and disposal of the exhausted Terphenyl, hydrogenated, that is treated through licensed waste handling companies. The amount of Terphenyl, hydrogenated disposed per year varies between a few kilos to 10 tonnes, depending on the size of the closed system, but this amount can increase drastically when the HTF is completely replaced (commonly, after 20 years of use or more). The typical

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[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0075
[18] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste
[19] PED. Current consolidated text: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0068-20140717&qid=1639053469715

disposal treatment is incineration, as in the case of other oils (e.g., lubricating oils), for energetic valorisation.

All these measures are focused on the release of Terphenyl, hydrogenated to the soil and the aquatic environment because, due to the low volatility of the substance, potential emissions to air are considered non-existent (less than 1 kilo per year, according to some respondents of the SEA questionnaire). Furthermore, the low boiling fraction generated during the deterioration of Terphenyl, hydrogenated is vented in closed loops to be internally incinerated (through the furnaces, steam boilers, flares, etc., installed in the sites).

There is no information from the SEA questionnaires related to the RMMs and OCs applied by companies that are using Terphenyl, hydrogenated as plasticiser or in other uses different to the HTF one.

B.9.2. Manufacturing

Companies are responsible for collecting information on the properties and uses of Terphenyl, hydrogenated if they manufacture or import into the EU above one tonne per year. This information is communicated through a REACH registration dossier.

According to the information from the REACH Registrations on ECHA's public dissemination website (ECHA, 2021a), there are currently 6 active registrants of Terphenyl, hydrogenated. The LR (Eastman Chemical BV) registered the substance in 2010, the other five co-registrants registered it by the 2018 deadline. At least two of those co-registrants are ORs representing non-EU companies; it is likely they are acting as internal ORs. The last update of the registration dossier was carried out by the LR in 2020. All registrations are full registrations, according to Article 10 of the REACH Regulation.

According to registration data on the ECHA public dissemination website (ECHA, 2021a), Terphenyl, hydrogenated is manufactured/used in the range of 10,000-100,000 tonnes per year.

Thereby Eastman as the LR has registered in the highest tonnage band (>1 000 tonnes per year), hence a major part of the volume used within the EU is attributed to the LR registration. One volume update was conducted by one of the member registrants to 100 – 1 000 tonnes per year.

The latest update of the LR's dossier took place on 9 of January 2020. Thereby the LR's manufacturing site was indicated to be "Newport (UK)". In the context of this restriction report it must be noted that the UK has left the EU on 31 of January 2020. Hence the manufacture of the LR is no longer taking place within the EU. Additionally, none of the Member Registrants manufactures within the EU.

Globally, the major production sites are located in the UK and in the US. Additionally, there are also production sites in China and the Middle East, whereas the volumes produced are noticeably lower. The major part of the volume used within the EU is imported from the UK and the US. A minor is imported from China or the Middle East.

The volumes used within the EU and the IU have been used as starting point of the environmental release estimation.

B.9.2.1. Occupational exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

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B.9.2.2. Environmental release

Terphenyl, hydrogenated is not manufactured within the EU and all of the Terphenyl, hydrogenated used is imported. To date, Terphenyl, hydrogenated is manufactured within the UK, the USA, China and the Middle East. Hence there are no releases to the environment in the EU related to the manufacture of the substance.

B.9.3. Use 1: Use as HTF at industrial sites

B.9.3.1. General information

Terphenyl, hydrogenated is used as HTF at multiple industrial and professional sites. Specific information on the releases to the environment of Terphenyl, hydrogenated during its use as HTF is obtained in the Exposure & Release Questionnaire (2018). The main objective of the low emission scenario was to present a realistic assessment whereas the use of the default information as given by the respective ERC represent a worst-case approach overestimating the actual emissions to the environment. Regarding the low emission scenario zero release is concluded. Thereby, the release fractions are based on information from sites where HTF-systems are running via the Exposure & Release Questionnaire (2018) which were evaluated carefully. Furthermore, information was submitted in the public consultation (20.06.2022 – 20.12.2022).

Additionally, measured data are available.

B.9.3.2. Exposure estimation

Information on the quantitative assessment
To estimate the exposure associated with the use as HTF at industrial sites the assessment is conducted based **on the installed volumes** instead of the imported volume used as HTF. Thereby, for the industrial use as HTF the highest installed volume at the largest plant in the EU is used as worst case: 1 200 tpa. For the assessment of the "Use as HTF at industrial sites" the annual use amount used at site as well as the daily use amount at site is set to 1 200 tonnes (please refer to

Table 15. Assumptions for Exposure Estimations).

However, it has to be emphasised that at most sites HTF systems with an installed volume of < 50 t are running. Within the EU only 10 sites have an installed volume > 50 t, at 50 sites the installed volume is > 10 t but < 50 t. Additionally, at 40 sites systems a volume < 10 t is installed. In total 100 sites within the EU run a system with Terphenyl, hydrogenated as HTF.

For detailed information please refer to **Table 6.** Installed HTF volume and number of sites in 2018 per EU Member State.

The total installed volume, taking into account all of the 100 sites, is determined to be 25 000 tonnes (**Table 4.** Installed base in the EU and uses as HTF).

Hence, taking into account the highest volume installed at a plant (1 200 tonnes) and assuming 100 sites will result in a **vast overestimation since the actual installed volume is exceeded approximately 5 times:**

Actual installed volume in the EU 25 000 t Theoretical installed volume taking into account the installed volume at the largest plant in the EU and the number of sites in the EU: 1 200 tonnes x 100 sites = 120 000 tonnes.

Table 15. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	89.7%		
Total tonnage used as HTF at ind. sites	6 700	tonnes per year	Not used in assessment. Assessment is based on installed volume
Number of emission days	365	days per year	
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	1 200	tonnes per day	Amount Terphenyl, hydrogenated in biggest HTF system installed in the EU.
Number of sites	100		Please refer to **Table 6.** Installed HTF volume and number of sites in 2018 per EU Member State.
Fraction released to air	0		**Low emission scenario** Exposure & Release Questionnaire (2018) Public consultation (2022) HTF system is a closed system hence exposure is negligible
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0		**Low emission scenario** Exposure & Release Questionnaire (2018) Public consultation (2022) HTF system is a closed system hence exposure is negligible
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scenario** Exposure & Release Questionnaire (2018) Public consultation (2022) HTF system is a closed system hence exposure is negligible
	0.05		**High emission scenario:** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	No solid waste is generated during the use of Terphenyl,		Reasonable worst-case assumption. Please also refer to qualitative assessment (Section B.9.4.3.).

Input factor/assumption	Value	Unit	Comment
	hydrogenated as HTF.		
Estimated release to air taking into account all sites	0 – 6 000	T per year	
Estimated release to wastewater taking into account all sites	0 – 6 000	T per year	
Estimated release to industrial soil taking into account all sites	0 – 6 000	T per year	
Estimated amount to solid waste for disposal taking into account all sites	0	T per year	
Total release taking into account all sites	0 – 18 000	T per year	

B.9.3.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.3.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.3.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 16**.

Table 16. Estimated indirect local exposure of human via the environment from industrial use as HTF in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	0	4.34	mg/kg bw/d
Fraction of total dose through intake of drinking water	0	0.0002	
Daily dose through intake of fish	0	4	mg/kg bw/d
Fraction of total dose through intake of fish	0	0.0002	
Daily dose through intake of leaf crops	0	0.12	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0	0.0000	
Daily dose through intake of root crops	0	1.78E+4	mg/kg bw/d
Fraction of total dose through intake of root crops	0	0.9948	
Daily dose through intake of meat	0	53.68	mg/kg bw/d
Fraction of total dose through intake of meat	0	0.003	
Daily dose through intake of milk	0	31.64	mg/kg bw/d
Fraction of total dose through intake of milk	0	0.0018	

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Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Local total daily intake of humans	0	1.79E+4	mg/kg bw/d
Man via environment - inhalation (systemic effects)	0	4.60E-2	mg/m^3
Man via environment - oral	0	1.79E+4	mg/kg bw/d

B.9.3.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 17**.

Table 17. Estimated environmental local exposure from industrial use as HTF in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	0	153.7	mg/L
$PEClocal_{freshwater\ sediment}$	0	4.86E+6	mg/kg dw
$PEClocal_{marinewater}$	0	15.37	mg/L
$PEClocal_{marinewater\ sediment}$	0	4.86E+5	mg/kg dw
$PEClocal_{STP}$	0	2.27E+3	mg/L
$PEClocal_{air}$	0	0.046	mg/m^3
$PEClocal_{agricultural\ soil}$	0	9.65E+5	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	0	1.1E+4	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	0	1.1E+3	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0	2.21E+3	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	0	2.63E+6	mg/kg ww

B.9.3.3. Exposure measurements

In order to obtain updated information on potential environmental emissions of Terphenyl, hydrogenated from industrial uses as HTF, a monitoring program was designed and developed at a number of industrial sites that use Terphenyl, hydrogenated in this application. Companies that participated in this program were requested to collect both air and soil samples, from locations at which releases of Terphenyl, hydrogenated could be regarded to be more likely.

The technical part of the project has been coordinated by the Institute of Occupational Medicine (IOM) in Edinburgh[20], UK. For the purpose of collecting environmental samples, the following material was used:

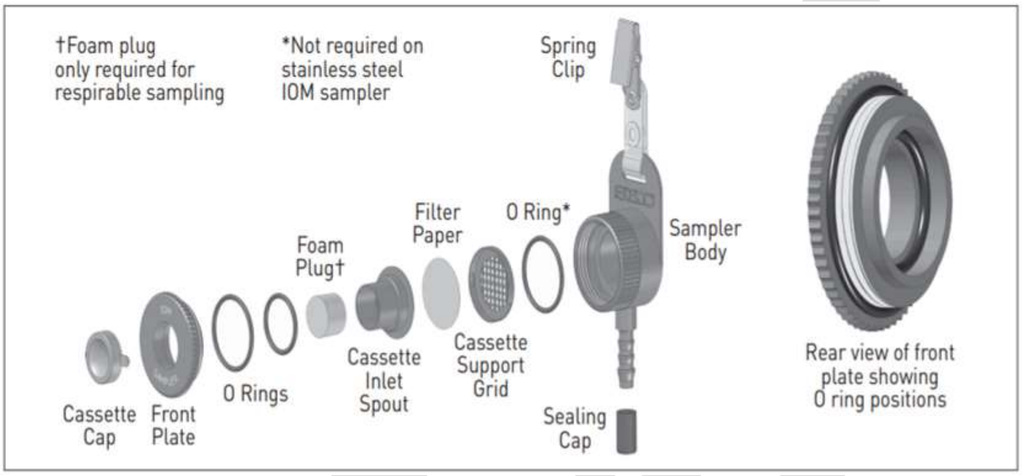
- IOM Samplers
- Sample Pumps (including chargers): SKC 224-SMTXM / SKC AirCheck Essential
- SKC Tubing
- PTFE Filters
- Calibrators

[20] IOM | Institute of Occupational Medicine (iom-world.org)

- Sample Transport Holders
- Tubes for Soil Samples, where relevant
- Chain Of Custody Paperwork

The IOM sampler is designed and closely adheres to the definition for sampling of inhalable dust given in EN481 (CEN, 1995). To fit a filter, the front plate is unscrewed. The cassette, comprising the inlet spout and filter support grid can then be removed by pulling forward gently. The two halves of the cassette clip together and can be separated with gentle pressure. Once separated, a PTFE filter is placed in the support grid. The inlet spout is snapped into the support grid making sure it is seated down properly. The cassette is then replaced into the body of the sampler and the front plate screwed on firmly so that all of the O-ring seals are compressed, thus ensuring there are no leaks (see **Figure 2**).

Figure 2. IOM sampler components



In this monitoring program, and in order to avoid any contamination of the PTFE filter, the cassettes were prepared in the IOM laboratory and delivered to the monitoring sites using sample transport holders[21]. Therefore, site staff in charge of the monitoring process only need to put the cassettes into the body of the sampler and to close it by screwing the front plate. At the end of the monitoring process, the cassette is extracted from the body of the sampler and is returned to the IOM laboratory, for analysis purposes, inside the same sample transport holders.

The collection of samples was performed on a best effort basis by site staff. Instructions from the technical partner were followed in order to ensure adequate sampling and chain of custody of collected samples. Air samplers were placed in the vicinity of the heat transfer system, near locations in which it was considered more likely that unintended emissions may occur (e.g., pumps, valves, flanges). In addition, each site collected one sample at an area in which no exposure to Terphenyl, hydrogenated is expected. Measurements were run for a minimum of 4 hours at a flow rate of approximately 2 litre/min. Finally, samples were labelled and stored until delivery to the IOM laboratory for analysis.

Soil samples are collected from an area as close as possible to points in which it is reasonably expected (or known) that leaks from the heat transfer system may have occurred in the past. Where possible, minimum 1.5 kg/samples were collected, spiked down until minimum 10 cm from the surface. It must be underlined that collection of soil samples was rare, since the vast majority of heat transfer systems currently operating are located on concrete floors, which makes it impossible to collect reliable soil samples.

[21] The original plan in this environmental monitoring program for Terphenyl, hydrogenated, which was scheduled to start in March 2020, was to have an IOM technician present on site when the samples were collected. However, this was not possible due to the Covid-19 pandemic.

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Adequate chain of custody and sample tracking methods have been put in place. The Chain of Custody Form requires, as a minimum:

- Start/End time and date
- Flow rate at the start/end and during sampling
- Sample number (this will be provided on the sample cassette supplied)
- Brief description of the location in which the sampler was placed
- Basic weather conditions (for external measurements)

The NIOSH method 5021 (CDC, 1994) for o-terphenyl is based on GCMS analysis from material collected using a PTFE filter. This was the analytical method used for determination of Terphenyl, hydrogenated collected in the air samples. A pure Terphenyl, hydrogenated sample was used as pattern to compare results obtained from the sites. As stated in the NIOSH method 5021, o-terphenyl is used as a calibration standard. In this way, it has been possible to identify any terphenyl peaks present and quantify them as o-terphenyl.

There are limitations with this method as IOM can report what is found but cannot guarantee that all terphenyls present in the air will be trapped on the filter, therefore, there may be other compounds present in the air that IOM cannot detect.

This method has been applied to air samples (PTFE filters for the sampling of inhalable dust) and soil samples (bulk). No determination of o-terphenyl in liquid samples was performed during the exposure measurements, although the method used in the analysis of liquid samples would be the same.

There are no standard analytical methods for the identification of the other main individual components of Terphenyl, hydrogenated, as m-terphenyl or p-terphenyl. In fact, the NIOSH pocket guides to chemical hazards for o-terphenyl, m-terphenyl and p-terphenyl (CDC, 2019) refer to the NIOSH 5021 analytical method for o-terphenyl as common measurement method.

For this reason, the Dossier Submitter recommends assuming the highest concentration of o-terphenyl (7.1%, detected by GC/MS analysis) provided in the REACH registration dossier of Terphenyl, hydrogenated (ECHA, 2021a) to calculate the concentration of Terphenyl, hydrogenated from the results obtained for o-terphenyl. Although this is not a direct method for the identification and quantification of Terphenyl, hydrogenated, it can give an idea of the concentration of Terphenyl, hydrogenated in the samples.

A total of 13 plants participated in this monitoring exercise.

The results of the air measurements are shown in the next table (**Table 18**):

Table 18. Summary of results of air measurements

Site	Location	Terphenyl, hydrogenated (as o-terphenyl)	
		µg	mg/m³
S-01	Non-exposure area	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
	Pump 3	<0.4	<0.001
S-02	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
	Pump 3	<0.4	<0.001
S-03	Equipment 1	<0.4	<0.001

	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
S-04	Pump 1	<0.4	<0.003
	Pump 2	<0.4	<0.001
S-05	Non-exposure area	<0.4	<0.001
	Expansion tank	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
S-06	Non-exposure area	<0.4	<0.001
	Pump system	<0.4	<0.001
S-07	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-08	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-09	Non-exposure area	<0.4	<0.001
	Pump	<0.4	<0.001
S-10	Non-exposure area	<0.4	<0.001
	Pump 1	<0.4	<0.001
	Pump 2	<0.4	<0.001
S-11	Non-exposure area	<0.4	<0,001
	Pumps	<0.4	<0,001
	Transport pipes	<0.4	<0,001
S-12	Non-exposure area	<0.4	<0,001
	Pump	<0.4	<0,001
S-13	Non-exposure area	<0.4	<0,001
	Pump	<0.4	<0,001

As it can be seen from **Table 18**, the presence of o-terphenyl was not determined above the reporting limit (0.4 µg) in any of the measurements carried out, neither in the areas of possible exposure nor in the areas of non-exposure. Therefore, it can be concluded that no emissions of Terphenyl, hydrogenated were detected in any of the monitoring sites.

It is interesting to note that during the measurements performed in the exposure area (pump) on Site S-06, there was a minor leakage of Terphenyl, hydrogenated (few drops – see Picture 9 below). However, no o-terphenyl was detected in the results of the corresponding sample analysis. This observation is interesting because it suggests that releases of Terphenyl, hydrogenated are possible, even if they are not detected via air sampling. Indeed, the low volatility of Terphenyl, hydrogenated would explain the fact that no o-terphenyl was detected in the relevant sample for this site. Also, the fact that air monitoring was limited to a relatively reduced time (4 hours in one single sampling event at each site) can explain the fact that no o-terphenyl was detected in any of the air samples collected. However, a closer evaluation of the situation at some sites (e.g., S-06, Picture 9) suggests that releases of Terphenyl, hydrogenated could be relatively frequent.

It should be noted that, according to the responses to the SEA questionnaires, these spills are always accidental in nature and are dealt with immediately: the leak is repaired and the released material is cleaned up and disposed of. These measures are also listed in Appendix

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5 on the strictly controlled closed system condition. Therefore, they will be mandatory for all plants operating heat transfer systems using Terphenyl, hydrogenated as HTF.

The results of the soil measurements are shown in the next table (**Table 19**):

Table 19. Summary of results of soil measurements

		Terphenyl, hydrogenated (as o-terphenyl)		
Code	**Location**	**µg**	**mg/kg**	**%**
S-01	Hot Transfer System 1	2 033.3	1 873.5	0.19
	Hot Transfer System 2	2.5	1.9	< 0.01

Site S-01 is the only installation, among the 13 included in the monitoring program, in which some sections of their heat transfer systems (Terphenyl, hydrogenated filling points) are not placed on concrete floor, which has allowed for soil samples to be taken. It has to be noted that this fact will be corrected when Appendix 5 is in force, as the heat transfer systems shall be installed over an impermeable surface (e.g., concrete) to reach the condition of strictly controlled closed systems.

In this case, the amount of o-terphenyl in the samples was above the reporting limit (1.0 µg) and it has been detected in the IOM laboratory analyses. This suggests that potential unintended (accidental) Terphenyl, hydrogenated emissions to soil could occur from heat transfer systems, reinforcing the earlier comments related to the visual analysis of some of the pictures collected at sites that have participated at the monitoring campaign.

Below is a brief description of the monitored heat transfer systems per site.

Table 20 shows the number of monitoring sites per country:

Table 20. Number of monitoring sites per country

Country	Number of sites
Italy	5
Netherlands	4
Belgium	1
Finland	1
Germany	1
Poland	1

Site S-01 is dedicated to the production of basic chemicals and operates three heat transfer systems, dated 1985, 1997, and 2007. The total volume of Terphenyl, hydrogenated operated by these systems is 60 m^3. The three systems have an expansion hot oil tank and a drain tank, and they are heated with natural gas. The operating temperature range is from 220 to 310°C and the pressure is 7 barg.[22] The low boiling components are vented to the process vent systems, they are partly condensed and the non-condensable part is transferred to the waste gas incinerator and the steam boilers for elimination. Terphenyl, hydrogenated degraded is drained and sent to an authorised external waste handler.

[22] Barg is the unit for the measurement of gauge pressure. Gauge pressure is measured against the ambient pressure. Therefore, it is equal to absolute pressure minus atmospheric pressure. Moreover, barg is the unit for the measurement of the pressure given by absolute pressure minus atmospheric pressure.

Figure 3. Air sample point in Site S-01

Figure 4. Soil sample point in Site S-01

Site S-02 and site S-03 belong to the same company, that is dedicated to the production of fuels and petrochemicals. Site S-02 runs two heat transfer systems, dated 1979 and 2000, operating at a temperature range of 280-340°C and a pressure of 18 barg, with a total volume of Terphenyl, hydrogenated of 1,300 tonnes. Both systems have expansion tanks, pumps with mechanic seal systems, and a common buffer storage tank for the draining process. The low boiling components are vented to flare and the Terphenyl, hydrogenated degraded is disposed for waste incineration. Site S-03 has only one heat transfer system, dated in 2018, that operates at 330°C and a pressure of 13.5 barg. The Terphenyl, hydrogenated volume used in this system is 250 tonnes. The installation is very similar to the one at Site S-02. In these sites was not possible to collect samples in non-exposure areas.

Figure 5. Air sample point in Site S-02

Figure 6. Air sample point in Site S-03

Site S-04 is dedicated to the manufacture of basic chemical products (phenols and aromatics). The site includes one heat transfer system that operates at a maximum temperature of 328°C and a pressure range from 400 to 1 000 kPa, using 230 tonnes of Terphenyl, hydrogenated. The system is 40 years old and has a collection tank, two drain tanks, and sealed pumps and valves. The low boiling components are vented to a gas combustion unit and the Terphenyl, hydrogenated degraded is sent to an authorised external waste company. In this site was not possible to collect samples in non-exposure areas.

Site S-05 operates only one heat transfer system with 25 m^3 of Terphenyl, hydrogenated, that runs at a maximum temperature of 310°C and a maximum pressure of 6 barg. The company produces basic chemical products and the heat transfer system is dated in 1997.

The system has an expansion tank and pumps are sealed. The degraded Terphenyl, hydrogenated is drummed and sent to a waste processor to be disposed.

Figure 7. Air sample point in Site S-05

Site S-06 is an energy producer that operates a heat transfer system composed of a biomass heater and an ORC turbine. The system contains 18 m^3 of Terphenyl, hydrogenated and it is in operation since 2014, running at a maximum temperature of 305°C and a pressure of 7 barg. Installation includes an expansion tank, pumps and valves with mechanical seals, and a collection vessel. All the vent points are collected to the heater to burn the low boiling components. As previously mentioned, a leak of Terphenyl, hydrogenated was detected at this site in the course of the environmental monitoring.

Figure 8. Air sample point in Site S-06

Figure 9. Terphenyl, hydrogenated leakage and leakage point at Site S-06

Site S-07 is dedicated to the manufacture of basic chemical products. The site runs three heat transfer systems operating for more than 30 years. The volume of Terphenyl, hydrogenated used in circulation within the system varies from 50 to 190 m^3, depending on the system. The operating temperature range is 285-315°C and the pressure range is 2-4 barg. All of the systems have collection and expansion vessels, and centrifugal pumps with mechanical seals for fluid circulation. Low boiling components are vented in closed loops to process vents collection networks, that deliver the vents to furnaces for incineration. Finally, the disposed Terphenyl, hydrogenated is collected in closed-drain systems and then sent for incineration along with liquid organic wastes from the plant.

Figure 10. Air sample point in Site S-07

Site S-08 is operated by an energy producer. It includes a single heat transfer system composed of a biomass heater and an ORC turbine. The system contains 18 m^3 of Terphenyl, hydrogenated and it has been active for 5 years, running at a maximum temperature of 305°C and a pressure of 6 barg. It has an expansion tank, pumps and valves with mechanical seals, and a collection vessel. All the vent points are collected to the heater to burn the low boiling components.

Figure 11. Air sample point in Site S-08

No specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer).

Site S-10 is a PET producer that is operating a heat transfer system with a volume of Terphenyl, hydrogenated of 100 m^3 and an operating age of 24 years. The system is running at a maximum temperature of 333°C and a pressure range of 5 to 7 barg. All Terphenyl, hydrogenated returning from the different sub-loops is collected in an expansion vessel. From this, the Terphenyl, hydrogenated is pumped into the furnace coils and subsequently discharged to the main supply header. The expansion tank, main-loop-pumps, sub-loop-pumps, and drain-tank are all equipped with dams in order to collect any spills of Terphenyl, hydrogenated. Finally, the low boilers are removed batch-wise with the aid of a low-boiler removal skid. Therefore, the system can be considered completely closed.

Figure 12. Air sample point in Site S-10

Site S-11 is dedicated to the production of plastics machinery components (mainly conveyor belts). The site is operating a single heat transfer system with two heaters and four pumps connected each one to a different distribution line to the user's machines. The system contains 10 m^3 of Terphenyl, hydrogenated and it is operating since 1998, running at a maximum temperature of 300°C and a pressure of 3.5 barg. Installation includes a collection vessel, pumps and valves with mechanical seals, and an expansion tank. The low boilers are collected and treated by an external maintenance company.

Figure 13. Air sample point in Site S-11 (pumps)

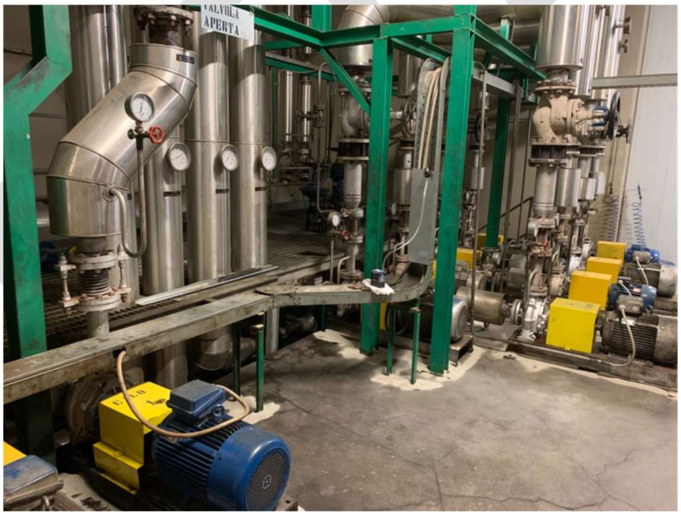

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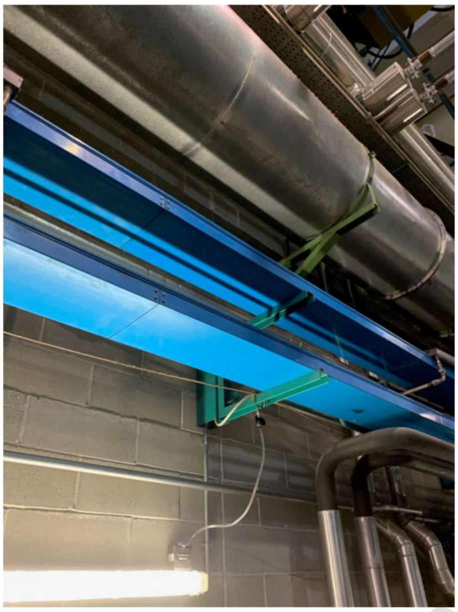
Figure 14. Air sample point in Site S-11 (transport pipes)



Site S-12 is a producer of PET resin that operates a single primary heat transfer system that feeds to other four smaller secondary systems. The overall equipment contains 70 m^3 of Terphenyl, hydrogenated and it is in operation since 2005, working at a pressure of 5 barg with a maximum temperature of 335°C. The system includes one storage tank and an expansion tank where low boilers are vented and later collected in a separate tank. These degraded products of Terphenyl, hydrogenated are disposed by authorized disposal companies with the required permits.

Site S-13 is an energy producer that operates a single heat transfer system composed of a biomass heater and an ORC turbine. The system is operating for 14 years with a volume of Terphenyl, hydrogenated of 65 m^3, at a maximum temperature of 310°C and a pressure of 3 bargs. It includes an expansion tank and a collection vessel, in which the low boilers are collected and disposed.

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Figure 15. Air sample point in Site S-13

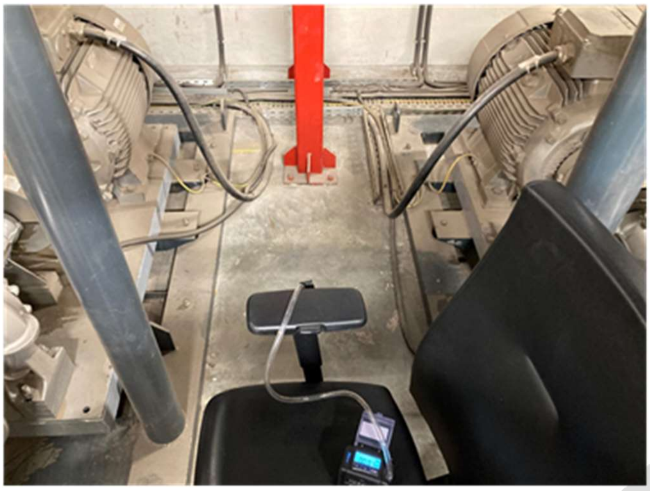

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Table 21 shows a summary of the main characteristics of the monitoring sites:

Table 21. Summary of the monitoring sites

Site	Number of heat transfer systems measured	Age of the heat transfer systems (years old)	Volume of Terphenyl, hydrogenated (m^3)	Operating Temperature (°C)	Operating Pressure (barg)
S-01	3	36, 24, 14	60	220 - 310	7
S-02	2	42, 21	1,300	280 - 340	18
S-03	1	3	250	330	13,5
S-04	1	40	230	328	3 - 9
S-05	1	24	25	310	6
S-06	1	7	18	305	7
S-07	3	30	50 - 190	285 - 315	2 - 4
S-08	1	5	18	305	6
S-09	-	-	-	-	-
S-10	1	24	100	333	5 - 7
S-11	1	24	10	300	3.5
S-12	1	17	70	335	5
S-13	1	14	65	310	3

B.9.3.4. Disposal of Terphenyl, hydrogenated when used as HTF

According to the information provided by the respondents to the SEA questionnaire, the disposed Terphenyl, hydrogenated comes from different sources:

- Periodical collection of degradation/decomposition products
- Complete drain of the heat transfer system
- Sampling of Terphenyl, hydrogenated for periodic quality control
- Dismantling of the heat transfer system
- Spills and leakages

Terphenyl, hydrogenated partially degrade at high temperature and, for this reason, a periodical collection of the decomposition products and a consequent refill with pure Terphenyl, hydrogenated is needed. The degradation products of Terphenyl, hydrogenated (mainly low boiling fractions) are collected into a vent line, condensed, and sent to a dedicated collection vessel. This equipment is part of the closed system, so there is no environmental exposure to these by-products. These degraded products are water fraction/emulsion with Terphenyl, hydrogenated.

The renewal of the Terphenyl, hydrogenated (overall annual volume of 2 275 tonnes) in the heat transfer system is required because the substance begins after many years in service to age (in some cases until 20 years), resulting in degradation products, an increase in viscosity, and solids begin to form. The overall heat transfer performance of the system can become less efficient. In addition, the elevated viscosity and solids content will result in accelerated fluid degradation[23]. Once the fluid quality has been analysed and found to be compromised, the system will need to be drained.

[23] Article-CHEmarch13-Heat-Transfer_0.pdf (therminol.com)

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After the fluid has been cooled, it can safely be drained via pumps through the use of appropriate procedures and Personal Protective Equipment (PPE) from the system into storage tanks for disposal. According to the feedback during the stakeholder consultations, the removal of the fluid from the system as well as the refill takes place in sealed and contained areas. Furthermore, the storage tanks are part of the closed system, so there is no environmental exposure to the drained Terphenyl, hydrogenated.

Periodic sampling of Terphenyl, hydrogenated is necessary to control and evaluate the quality of the Terphenyl, hydrogenated installed in the heat transfer system. The Terphenyl, hydrogenated generated during the sampling process is collected in little containers.

According to the responses to the SEA questionnaires, spills of Terphenyl, hydrogenated in the heat transfer systems are occurring very rarely or are unlikely, and they are therefore considered to be incidents. All the main equipment in the closed system, like pumps, valves, tanks, etc., are equipped with containment devices in order to avoid any spills of Terphenyl, hydrogenated, so no exposure to the environment is expected. However, if they eventuate residual Terphenyl, hydrogenated on sealed/contained area is being removed by using absorbent material, such as mats or loose media. Once any remaining fluid has been absorbed, this material is removed for appropriate disposal.

The disposed products are transported to certified and qualified waste operators, directly inside the collection tanks, after drumming into barrels, or by truck. Piping and hoses of the trucks, collection tanks, and barrels are cleaned in the same disposal companies and the solvent-water mixture is disposed together with the received product.

The disposal of degraded, drained, or sampled Terphenyl, hydrogenated is similar to the disposal of e.g., lubricating oils. The waste code used is 14 06 03 "Other solvents and solvent mixtures", according to the table of equivalence of Annex III to Regulation 2150/2002[24].

Afterward, the disposal product is incinerated in plants that are known as Waste-To-Energy (WTE) sites, for recovering its calorific value. In this process, the heat from the combustion generates superheated steam in boilers, and the steam drives turbogenerators to produce electricity. Modern European Waste-to-Energy plants are clean and safe, meeting the strictest emission limit values placed on any industry set out in the EU Industrial Emissions Directive[25]. It should be noted that Terphenyl, hydrogenated has a calorific value of approximately 44 MJ/kg, which is in the same range as currently used fuels (e.g., diesel, petrol, crude oil, LPG)[26]. It means that the energy recovery of these disposal products is an efficient process.

In case a plant has to be dismantled, the whole heat-transfer system needs to be emptied, flushed, rinsed, and cleaned prior to dismantling. The cleaning and rinsing procedure has been described and monetized as well in the Annex E.4.1.1. "Substitution and Investment Costs" for the Economic Impacts of RO3.

B.9.3.5. Qualitative assessment

The overall qualitative assessment is carried out collectively for all HTF-related uses as indicated below:

- Use as HTF at industrial sites, and
- Laboratory analysis.

Please refer to Chapter B.9.5.3.

[24] Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics (Consolidated version: 18.10.2010).

[25] The Industrial Emissions Directive - Environment - European Commission (europa.eu)

[26] Heat values of various fuels - World Nuclear Association (world-nuclear.org)

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B.9.4. Use 2: Laboratory analysis

B.9.4.1. General information

Terphenyl, hydrogenated is used as HTF at multiple industrial sites. At all sites samples are taken on a regular basis (once a year) to be analysed by the company selling the HTF. Table 6 provides an overview on the number of systems installed and installed volume per EU Member State. In total 100 HTF systems are installed in the EU. As a worst-case assumption 150 sites within the EU are assumed in the assessment. Of those sites each site provides one 1 L sample for analysis per year. Specific information on the releases to the environment of Terphenyl, hydrogenated during analysis of HTF samples is obtained in the Exposure & Release Questionnaire (2018).

B.9.4.2. Exposure estimation

Table 22. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.002%		
Total tonnage used in laboratory analysis	0.15	tonnes per year	Based on the assumption that each site within the EU sends a 1 L sample for analysis
Number of emission days	20 - 100	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 Exposure & Release Questionnaire (2018)
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	0.0015 - 0.0075	tonnes per day	Exposure & Release Questionnaire (2018)
Fraction released to air	0.001		**Low and high emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0		**Low emission scenario** Exposure & Release Questionnaire (2018): No wastewater is produced during quality control operations on taken HTF samples. Wastewater which is generated during equipment cleaning is incinerated.
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.00025		**Low and high emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	0.15	kg per year	
Estimated release to wastewater	0 – 7.5	kg per year	
Estimated release to industrial soil	0.038	kg per year	
Estimated amount to solid waste for disposal	n.a.	kg per year	

Input factor/assumption	Value	Unit	Comment
Total release	0.19 – 7.69	kg per year	

B.9.4.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.4.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.4.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 23**.

Table 23. Estimated indirect local exposure of human via the environment from laboratory analysis in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	6.44E-12	2.71E-05	mg/kg bw/d
Fraction of total dose through intake of drinking water	0	0.0002	
Daily dose through intake of fish	1.96E-11	4.50E-04	mg/kg bw/d
Fraction of total dose through intake of fish	0	0.0040	
Daily dose through intake of leaf crops	2.19E-07	1.09E-06	mg/kg bw/d
Fraction of total dose through intake of leaf crops	3.03E-01	9.73E-06	
Daily dose through intake of root crops	2.64E-08	1.11E-01	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0365	0.9910	
Daily dose through intake of meat	3.01E-07	3.36E-04	mg/kg bw/d
Fraction of total dose through intake of meat	0.4161	0.0030	
Daily dose through intake of milk	1.77E-07	1.98E-04	mg/kg bw/d
Fraction of total dose through intake of milk	0.2447	0.0018	
Local total daily intake of humans	7.23E-07	1.12E-01	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.14E-07	4.85E-07	mg/m^3
Man via environment - oral	7.24E-07	1.12E-01	mg/kg bw/d

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B.9.4.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 24**.

Table 24. Estimated environmental local exposure from laboratory analysis in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	2.3E-12	9.61E-4	mg/L
$PEClocal_{freshwater\ sediment}$	7.27E-8	30.38	mg/kg dw
$PEClocal_{marinewater}$	4.53E-13	9.61E-5	mg/L
$PEClocal_{marinewater\ sediment}$	1.43E-8	3.038	mg/kg dw
$PEClocal_{STP}$	0	0.014	mg/L
$PEClocal_{air}$	1.14E-7	4.85E-7	mg/m^3
$PEClocal_{agricultural\ soil}$	1.4E-6	6.032	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	1.19E-7	1.369	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	2.36E-8	0.137	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	2.36E-7	0.274	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	3.91E-6	16.45	mg/kg ww

B.9.4.3. Qualitative assessment

Introduction

The overall qualitative assessment is carried out collectively for all HTF-related uses as indicated below:

- Use as HTF at industrial sites, and
- Laboratory analysis.

General description

The majority of Terphenyl, hydrogenated (approx. 90 %) is used as Heat Transfer Fluid (HTF) at industrial sites. A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater)

Thereby, the Terphenyl, hydrogenated does not need to be formulated in order to be used as HTF. Hence, a formulation scenario is not necessary.

However, the installed HTF is analyses on a regular basis (usually once per year) by the supplier to determine its lifetime. Therefore, samples are taken and send to be analysed.

Since the Terphenyl, hydrogenated is not incorporated into/onto an article upon use no service life scenario is necessary.

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Nevertheless, the Terphenyl, hydrogenated in the system needs to be replaced at one point, hence the handling of the waste is important when used as HTF.

The two uses indicated before are covered in this qualitative assessment.

Environmental exposure

For the uses assessed information is received via an Exposure & Release Questionnaire (2018) which was send by the lead registrant. Furthermore, very specific information was submitted in the public consultation (20.06.2022 – 20.12.2022).

In general, emissions were estimated using the default release factors as given by the assigned ERCs. Further, the emissions associated with the use as HTF at industrial sites and the laboratory analysis of the HTF samples are estimated using the specific information that were received via the Exposure & Release Questionnaire (2018) and the public consultation (20.06.2022 – 20.12.2022).

Moreover, an applicable ESVOC SpERC is available. However, based on the obtained information it was decided that the ESVOC SpERC is not suitable for the use as HTF.

Additionally, measured data are available for the use as HTF at industrial sites.

	Ind. use as HTF	Laboratory analysis
Total tonnage used per year (t/y)	*Not relevant for the assessment*	0.15
Maximum tonnage installed at a site (t/d)	1 200	*Not relevant for the assessment*
Estimated release to air (kg/y)	0 – 6000 000	0.15
Estimated release to wastewater (kg/y)	0 – 6000 000	0 – 7.5
Estimated release to industrial soil (kg/y)	0 – 6000 000	0.038
Estimated amount to solid waste for disposal (kg/y)	0	n.a.
Total release (kg/y)	0 – 1 800 000	0.19 – 7.69
Percentage of used volume which is released (%)	150	0.13 – 5.13

Looking at both uses, the laboratory analysis is associated with a low release. Although no specific information is available regarding the treatment of waste it is reasonable to assume that waste water and waste air will be treated before being released to the environment. Further, a release to the soil is very unlikely as is also indicated by the very low release estimate of 0.038 kg/y.

However, no information regarding solid waste for disposal is available. Since the analysis is taking place at the HTF supplier's laboratory, it is assumed that all waste will be disposed of

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accordingly. Most likely all waste will be incinerated due to the high caloric value of Terphenyl, hydrogenated.

Especially for the use as HTF at industrial sites very high releases (18 000 tpa) are estimated in the high emission scenario using the ERC defaults. However, it needs to be emphasised that the result is a vast overestimation and not realistic as outlined below:

- For the assessment the installed volume was used. Thereby, for the industrial use as HTF the highest installed volume at the largest plant in the EU is used as worst case: 1 200 tpa (please refer to
- **Table** 15. Assumptions for Exposure Estimations).
  However, it has to be acknowledged that at most sites HTF systems with an installed volume of < 50 t are running. Within the EU only 10 sites have an installed volume > 50 t, at 50 sites the installed volume is > 10 t but < 50 t. Additionally, at 40 sites systems a volume < 10 t is installed. In total 100 sites within the EU run a system with Terphenyl, hydrogenated as HTF. For detailed information please refer to **Table 6.** Installed HTF volume and number of sites in 2018 per EU Member State.
  The total installed volume, taking into account all of the 100 sites, is determined to be 25 000 tonnes (**Table 4.** Installed base in the EU and uses as HTF).
  Hence, taking into account the highest volume installed at a plant (1 200 tonnes) and assuming 100 sites will result in a vast overestimation since the actual installed volume is exceeded approximately 5 times: 1 200 tonnes x 100 sites = 120 000 tonnes.
- Based on the feedback from the stakeholder consultation and individual communication it is determined that in 2020 approx. 6 700 tonnes of Terphenyl, hydrogenated were sold on the EU market, from which around 5 % were used for "top-up" of HTF plants. The top-up demand is driven by the degradation rate of the HTF and the separated low-boiling and high-boiling degradation products. It needs to be understood that the refill cannot be associated with loss of PHT into the environment. In general, this is also contradicting to the estimated releases of the high emission scenario, leaving the fact aside that the release cannot be higher than the amount that is used or in this case "in use".

Consequently, the high emission scenario for the use as HTF at industrial sites is not taken into account for the following evaluation.

Admittedly, it is quite uncommon that an use which falls under REACH Article 10 results in zero release. However, the public consultation showed in specific that the industry is well aware of the fact that it is essential to prevent any release of Terphenyl, hydrogenated into the environment when used as HTF. Further, the public consultation revealed that industries are already undertaking major efforts to minimise any release. There are no systematic releases when Terphenyl, hydrogenated is used as HTF. Only accidental releases which occur rarely are anticipated.

The information received is summarized in the following sub-chapter (Specific information regarding potential emission obtained via the public consultation).

Specific information regarding potential emission obtained via the public consultation

In general, all respondents are well aware that it is crucial to not release any Terphenyl, hydrogenated into the environment.

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1. System

All respondents state that Terphenyl, hydrogenated is used in a closed system and state that under normal operating conditions there are no emissions to the environment. All equipment is based on Directive 2014/68/EU (Pressure Equipment Directive – PED)27. The PED applies to all HTF plants and already sets requirements to these installations in terms of safety.

It is explained that the HTF is circulated in a closed system including a closed, inert expansion tank which a Nitrogen blanket in which all the system vents are collected, pumps with mechanical seals/double mechanical seals or seal-less pumps, flanges equipped with safety covers, the fluid level, pressure, and temperature is monitored, storage vessels are equipped with containment system, etc. One respondent said that pumps used are hermetic pumps which leaks towards inside of pump. All of these measures ensure that no direct or indirect with the Terphenyl hydrogenated and nothing is emitted to the environment.

Furthermore, it is indicated by multiple respondents that the HTF plant is based on concrete floors and bunds with separate sewers. Further, one respondent said that the condition of the floors is regularly checked as well. Only one respondent stated that not all pipelines are over contained, leak-tight ground. However, they further said that any leak is easily noticed. Another respondent indicated that in the unlikely case of accidental leakage (e.g., dripping from flanges once or twice per year), leakage is collected in an oily water system. However, since the sampling of oily water is done on a regular basis HTF leakage would be noticed.

Although the HTF plant is controlled remotely all parts of the HTF plant are controlled on a regular basis. One respondent indicated that all pumps are checked weekly, and seals are checked biweekly to control their status and avoid leakages. Further it was mentioned by respondents that leakage (performance) tests of joints are performed after every maintenance operation. Another respondent said that the whole plant is under video surveillance and the most critical parts are even covered by thermal imaging cameras. Furthermore, it is stated that a third party periodically inspects the heat transfer system according to PED.

Another respondent stated that every 5 years a hazard and operational study (hazop) is performed, and the risks possibly found are corrected to reduce the risks and increase the safety of the system.

Moreover, one respondent indicated an Emergency Shutdown system which is connected to a continuous monitoring system is in place to ensure the safe operation of the system at all times.

However, it was stated in the public consultation that emission of Terphenyl, hydrogenated is possible when filling up/ toping up/ refilling the system although the same respondent also indicated that no emissions of Terphenyl, hydrogenated were found in analysed samples, though.

Additionally, the HTF itself is analysed at least once per year. Therefore, a sample is provided to the HTF supplier. One respondent explained that sampling is conducted at their plant using a Dopak closed sampling system whereby a needle sticks through the rubber cap of the bottle to ensure that there is no contact of Terphenyl, hydrogenated with the operator and no emission to the environment. Another respondent stated that sampling is performed under strictly controlled conditions. Furthermore, the respondents are aware that personnel need to be trained and retrained on a regular basis. Training is required to enter the area meaning that all employees at the plant receive a specific,

[27] PED. Current consolidated text: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0068-20140717&qid=1639053469715

systematic training. One respondent also stated that a work permit system as well as written procedures for operation and maintenance are in place.

2. Waste

The light fraction of the HTF system is collected and cooled down. After that the vapour phase is burned on site in a vent gas incinerator/waste incinerator.

The liquid phase is sent for further treatment to a certified hazardous waste treatment plant where it is incinerated due to the high caloric value.

Once respondent also indicated that special filters are installed which filter polymerised particles to prolong the lifetime of the Terphenyl, hydrogenated.

It is explained in the public consultation that the replacement of the HTF can be realised without spills as the fluid to be replaced can be drained using the closed drain system to the drain and storage vessels. From these vessels, the fluid can be pumped into a road tank for proper disposal. The fluid for refilling of the system is pumped from the road tank directly into the storage vessel. In case of plant decommissioning, the HTF could be drained using the closed drain system to the storage vessel.

3. Accidental release

It is stated in the public consultation that any leakage is accidental and very rare.

One respondent explained that since 1980 the HTF system is running within incidents, leakages, or accident. Multiple respondents further stated that the plant is equipped with a leakage collection system. Moreover, all accidental spills of material will be reported in the internal risk management system. One respondent stated that all accidental eventual spills are immediately registered by the HSE manager.

One respondent said that all leakage is collected in an oily water system. He further stated that any dripping will be removed immediately and disposed of accordingly as dangerous waste.
Another respondent indicated that accidental small spills (e.g., drip leaks at gaskets) can be easily cleaned using absorbance materials which are disposed of as waste through authorized waste handlers. In general, Terphenyl, hydrogenated is incinerated then to use its high calorific value.

It is further stated by another respondent that, when there is a leakage, they collect everything until the leakage can be repaired.

As indicated before the industry is well aware of the fact that it is essential to prevent any release of Terphenyl, hydrogenated into the environment. Further, the public consultation revealed that industries are already undertake major efforts to minimise any release.

Conclusion

The releases associated with the laboratory use are regarded as very small (if any). Hence it is concluded that the laboratory use to determine the lifetime of the Terphenyl, hydrogenated used as HTF does not lead to inevitable emissions which need to be minimised.

Taking all information from the Exposure & Release Questionnaire (2018) and the public consultation into account it is safe to say that Terphenyl, hydrogenated is contained in a highly controlled, closed system when used as HTF.

All respondents are well aware that it is crucial to not release any Terphenyl, hydrogenated into the environment.

Consequently, emissions to the environment are regarded as highly unlikely during normal operations. There are no systematic releases when Terphenyl, hydrogenated is used as HTF. Only accidental releases which occur rarely are anticipated. Further, it was highlighted by multiple respondents in the public consultation that there are systems in place remove and deal with leakage appropriately.

It is hence concluded that the industrial use of Terphenyl hydrogenated as HTF does not lead to inevitable emissions. Further, it became clear that industry goes to great length to ensure that there is no emission during the running of the HTF system.

The findings are also supported by the exposure measurements which were conducted (for further information please refer to Section B.9.3.3.)

Nevertheless, a Guidance Document on Strictly Controlled Closed Systems (SCCS) is written which will ensure that all HTF system which are run with Terphenyl, hydrogenated fulfil the same standard of "zero emission".

The main points of the SCCS Guidance Document are summarized below.

SCCS Document

The heat transfer system using Terphenyl, hydrogenated as HTF shall implement the following RMMs (technical) and OCs (structural and organisational) to be considered compliant with the SCCS condition:

- Use of components and equipment (e.g., heat exchangers, piping, insulation, pumps, valves, gaskets, seals, relief devices, and instrumentation) compatible with Terphenyl, hydrogenated and the intended system temperature and pressure.
- The system shall be installed on an impermeable surface (e.g., concrete).
- The area under the system shall be coupled with general leakage collection systems (e.g., sloped floors, curbs, dikes, drainage systems) to divert potential leakage and runoff to a safe location.
- The drainage of contaminated effluents must be stored in closed systems.
- The process vessels and tanks shall be equipped with vents to prevent pressure build-up by gases.
- The venting and expansion lines shall be routed into collection systems and connected to air pollution control equipment.
- To prevent leaks from relief vents, rupture disks can be used in combination with safety valves.
- Existence of calamity basins/tanks to control potential accidents during the processes involving high volumes of PHT (filling and drain).
- The piping installation must be designed with appropriate and resistant materials to prevent breakages and welded construction must be used whenever possible.
- The piping lines shall be appropriately routed and/or suitable joints shall be installed to compensate for the thermal expansion.
- The number of flanges (connectors) must be minimised in the piping lines (only to accommodate essential equipment) and the gaskets must be effective.
- The installation of stop valves in the flow and return pipes is recommended.
- The use of magnetically driven or canned motor pumps, or pumps with double seals and/or a liquid barrier is recommended.
- The pump housings must be designed to withstand at least a maximum pressure of 16 bar.

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- The shaft seals of the pumps must be of proven suitability.
- It is recommended that pumps are surrounded by curbs to divert and collect the potential leaks from the shaft seal.
- Special valves (e.g., with bellow, with double packing seals, with sealing of the spindle feedthrough), flanges (e.g., with weld lip gaskets, with flat, raised, or tongue and groove faces), connections (e.g., metal-sealed, cutting and clamping rings), shall be used in the system.
- In case that standard components (pumps, valves, seals, etc.) are used in the system, containment devices shall be installed beneath them.
- The thermal insulation shall permit the quick detection of leaks at points where there is a high leaking risk.
- Special equipment shall be used at sampling points.
- Special containment measures shall be taken for the performance of processes out of the usual operational conditions of the system (e.g., filling, start-up, shutdown, drain)
- The system start-ups, shutdowns, and emergency stops shall be minimised.
- Operating limits for temperature, pressure, level of Terphenyl, hydrogenated, flow rates, and chemical composition of Terphenyl, hydrogenated shall be established and monitored.
- Leaking tests (e.g., hydraulic, painting with wetting agents, visual) shall be periodically performed and recorded, especially during and after processes out of the usual operational conditions of the system.
- Leakages shall be corrected and cleaned up immediately/promptly.
- A leaking control program shall be developed and implemented.
- The quality of Terphenyl, hydrogenated shall be periodically evaluated by sampling and analysis (minimum once a year).
- Terphenyl, hydrogenated and the material stained of it (e.g., samples, spills, drainages, dismantled equipment) shall be adequately disposed of (internally and/or externally).
- The low boiling fractions generated during degradation of Terphenyl, hydrogenated shall be evacuated from the system and adequately disposed of.
- Internal and external inspections of the system must be periodically performed by qualified personnel and the results shall be documented.
- The observations and deficiencies identified during the inspections shall be recorded and addressed.
- Appropriate written manuals, procedures, instructions and permits to work shall be developed for all of the processes performed in the system (including maintenance and repair), especially for those out of the usual operational conditions.
- These documents shall be available to the workers in a form and language they can understand.
- Maintenance, inspection, and training plans must be developed, periodically performed, and recorded.
- All of the operators and the maintenance and inspection teams shall be trained according to these procedures and instructions.
- The trainings shall include adequate information about the hazards associated with the use of Terphenyl, hydrogenated and the equipment, and information to avoid the release of the HTF into the environment.
- All of the processes performed in the system shall be executed by qualified workers.

These RMMs and OCs guarantee the closed behaviour of the installation, avoiding improper emissions to the environment. However, this list shall be considered non-exhaustive, as many

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other equivalent measures can be taken. Therefore, the above listed RMMs and OCs shall be considered exclusively as examples of good techniques.

B.9.5. Use 3: Use as HTF at professional sites

In December 2022, the LR has analysed his database to determine at how many sites HTF is used in a professional setting.

Thereby, it was determined that all sites receiving Terphenyl, hydrogenated as HTF are indeed industrial sites. Hence, the use of Terphenyl, hydrogenated as HTF at professional sites is no longer regarded as relevant.

B.9.6. Use 4: Formulation of adhesives and sealants

B.9.6.1. General information

Terphenyl, hydrogenated is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of Terphenyl, hydrogenated from formulation of adhesives/sealants is available. However, a FEICA / EFCC SpERC (FEICA / EFCC SPERC 2.1a.v3) is applicable for the refinement of the default assumptions.

FEICA / EFCC SpERC 2.1a.v3 describes the "Formulation of Solvent-borne and Solvent-less Adhesives / Sealants and Construction Chemical Products - non-volatile Substances"

It includes substances other than solvents which do not evaporate to a significant extent during formulation of the adhesive. Non-volatile ingredients are defined by a boiling point threshold of >250°C.

Thereby the following activities/processes are regarded as covered: storing, mixing, packaging, filling of substances (as part of preparations) and equipment cleaning, maintenance and associated laboratory activities

Further, this SpERC only covers indoor used and assumes that there is no water contact during the use. According to the SpERC factsheets 300 emission days per year can be assumed.

The release factors indicated are based on "Tolls et al. 2016. Estimating emissions from adhesives/sealants uses and manufacturing for use in environmental risk assessment. Intergr Environ Assess Manag, (Jan, 2016)".

B.9.6.2. Exposure estimation

Table 25. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	6.42%		
Total tonnage used for formulation of adhesives/sealants	480	tonnes per year	

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Input factor/assumption	Value	Unit	Comment
Number of emission days	100 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 FEICA / EFCC SPERC 2.1a.v3
Daily amount of Terphenyl, hydrogenated formulated at a site (local scenario)	1.6 - 4.8	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	0.0008		**Low emission scenario** FEICA / EFCC SPERC 2.1a.v3
	0.025		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.0002		**Low emission scenario** FEICA / EFCC SPERC 2.1a.v3
	0.02		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scenario** FEICA / EFCC SPERC 2.1a.v3
	0.0001		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.002 – 0.03		FEICA / EFCC SPERC 2.1a.v3
Estimated release to air	384 – 12 000	kg per year	
Estimated release to wastewater	96 – 9 600	kg per year	
Estimated release to industrial soil	0 - 48	kg per year	
Estimated amount to solid waste for disposal	960 – 14 400	kg per year	
Total release	1 440 – 36 048	kg per year	

B.9.6.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

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B.9.6.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.6.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 26**.

Table 26. Estimated indirect local exposure of human via the environment from formulation of adhesives or sealants in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	2.32E-5	6.95E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.25E-4	0.0002	
Daily dose through intake of fish	5.76E-3	0.576	mg/kg bw/d
Fraction of total dose through intake of fish	5.59E-2	0.0197	
Daily dose through intake of leaf crops	5.62E-4	0.018	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0055	0.0006	
Daily dose through intake of root crops	9.50E-2	28.5	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9221	0.9735	
Daily dose through intake of meat	1.06E-3	0.11	mg/kg bw/d
Fraction of total dose through intake of meat	0.0103	0.0038	
Daily dose through intake of milk	6.22E-4	0.065	mg/kg bw/d
Fraction of total dose through intake of milk	0.0060	0.0022	
Local total daily intake of humans	1.03E-1	2.93E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.93E-4	9.14E-3	mg/m^3
Man via environment - oral	1.03E-1	29.27	mg/kg bw/d

B.9.6.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 27**.

Table 27. Estimated environmental local exposure from formulation of adhesives/sealants in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{freshwater}$	8.2E-4	0.246	mg/L
$PEClocal_{freshwater\ sediment}$	25.93	7.78E3	mg/kg dw
$PEClocal_{marinewater}$	8.2E-5	0.025	mg/L

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{marinewater\ sediment}$	2.593	777.8	mg/kg dw
$PEClocal_{STP}$	0.012	3.626	mg/L
$PEClocal_{air}$	2.93E-4	9.14E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	5.151	1.54E3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	17.52	1.75E3	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	1.752	175.2	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	3.509	350.9	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	14.04	4.21E3	mg/kg ww

B.9.6.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in adhesives/sealants is carried out collectively for all uses as indicated below:

- Formulation of adhesives and sealants,
- Use of adhesives and sealants at industrial sites,
- Use of adhesives and sealants by professionals, and
- Service life of articles produced from use as plasticiser.

Please refer to Chapter B.9.9.4.

B.9.7. Use 5: Use of adhesives and sealants at industrial sites

B.9.7.1. General information

Terphenyl, hydrogenated is used as plasticiser in adhesives and sealants. Only little information on the releases to the environment of Terphenyl, hydrogenated from the industrial use of adhesives/sealants is available (received via the public consultation). For example, Terphenyl, hydrogenated is used by aerospace and defence industries since it is a constituent of sealant/adhesive formulations. It is for example used to seal fuel tanks and to seal pressurized aircraft cabins. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables).

Nevertheless, a FEICA SpERC (FEICA SPERC 5.1a.v3) is applicable for the refinement of the default assumptions.

FEICA / EFCC SPERC 5.1a.v3 describes the "Industrial use of non-volatile Substances in Solvent-borne and Solvent-less Adhesives / Sealants"

It includes substances other than solvents (non-volatiles) are defined by a boiling point threshold of >250°C.

The following activities are regarded as covered: Charging equipment, application of adhesive / sealant, curing, equipment cleaning, maintenance. Upon curing, substances are included into matrix without intended release to the environment.

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Further, this SpERC only covers indoor use and additionally, water contact during use is excluded. As indicated in the SpERC factsheet 300 emission days per year are assumed.

The release factors indicated are based on "Tolls et al. 2016. Estimating emissions from adhesives/sealants uses and manufacturing for use in environmental risk assessment. Intergr Environ Assess Manag, (Jan, 2016)".

B.9.7.2. Exposure estimation

Table 28. Assumptions for Exposure Estimation

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	5.14%		
Total tonnage used in adhesives/sealants at ind. sites	384	tonnes per year	
Number of emission days	20 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 FEICA SPERC 5.1a.v3
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	0.128 - 1.92	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.017		**Low emission scenario** FEICA SPERC 5.1a.v3
	0.5		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0		**Low emission scenario** FEICA SPERC 5.1a.v3
	0.5		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scenario** FEICA SPERC 5.1a.v3
	0.01		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0 – 0.06		FEICA SPERC 5.1a.v3
Estimated release to air taking into account all sites	6 528 – 192 000	kg per year	
Estimated release to wastewater taking into account all sites	0 – 192 000	kg per year	
Estimated release to industrial soil taking into account all sites	0 – 3 840	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	0 – 23 040	kg per year	
Total release taking into account all sites	6 528 – 410 880	kg per year	

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B.9.7.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.7.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.7.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 29**.

Table 29. Estimated indirect local exposure of human via the environment from industrial use of adhesives/sealants in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	2.84E-8	6.90E-2	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.81E-6	0.0002	
Daily dose through intake of fish	6.42E-8	1.153	mg/kg bw/d
Fraction of total dose through intake of fish	6.35E-6	0.004	
Daily dose through intake of leaf crops	9.57E-4	0.029	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.09	0.0001	
Daily dose through intake of root crops	1.17E-4	285	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0116	0.9907	
Daily dose through intake of meat	1.31E-3	0.896	mg/kg bw/d
Fraction of total dose through intake of meat	0.1295	0.0031	
Daily dose through intake of milk	7.73E-3	0.528	mg/kg bw/d
Fraction of total dose through intake of milk	0.7643	0.0018	
Local total daily intake of humans	1.01E-2	287.67	mg/kg bw/d
Man via environment - inhalation (systemic effects)	4.99E-4	1.50E-2	mg/m^3
Man via environment - oral	3.16E-3	287.6	mg/kg bw/d

B.9.7.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 30**.

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Table 30. Estimated environmental local exposure from industrial use of adhesives/sealants in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	7.52E-9	2.46	mg/L
$PEClocal_{freshwater\ sediment}$	2.38E-4	7.78E4	mg/kg dw
$PEClocal_{marinewater}$	8.48E-9	0.246	mg/L
$PEClocal_{marinewater\ sediment}$	2.68E-4	7.78E3	mg/kg dw
$PEClocal_{STP}$	0	36.26	mg/L
$PEClocal_{air}$	4.99E-4	0.015	mg/m^3
$PEClocal_{agricultural\ soil}$	6.18E-3	1.54E4	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	3.91E-4	3.5E13	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	4.41E-4	351.4	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	4.41E-3	711.3	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	0.017	4.21E4	mg/kg ww

B.9.7.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in adhesives/sealants is carried out collectively for all uses as indicated below:

- Formulation of adhesives and sealants,
- Use of adhesives and sealants at industrial sites,
- Use of adhesives and sealants by professionals, and
- Service life of articles produced from use as plasticiser.

Please refer to Chapter B.9.9.4.

B.9.8. Use 6: Use of adhesives and sealants by professionals

B.9.8.1. General information

Terphenyl, hydrogenated is used as plasticiser in adhesives and sealants. No specific information on the releases to the environment of Terphenyl, hydrogenated from the professional use of adhesives/sealants is available. However, a FEICA SpERC (FEICA / EFCC SPERC 8f.1a.v2) is applicable for the refinement of the default assumptions.

FEICA / EFCC SPERC 8f.1a.v2 describes the "Widespread use of non-volatile substances in adhesives / sealants and construction chemical products - outdoor"

It includes all ingredients which do not evaporate to a significant extent upon curing of the product. Non-volatile substances are defined by a boiling point threshold of >250°C.

Thereby it covers the application of adhesives, sealants and construction chemical products for a wide range of purposes by consumers and by professional uses. Adhesives and sealants are applied between two substrates. Upon application curing takes place either via a chemical reaction or via evaporation of a solvent. Construction chemical products cover the uses applied to buildings, their trim and fittings and construction purposes. Key processes may include: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities. Roller application or brushing, spraying (non-industrial), extrusion from a cartridge, dipping and pouring of articles.

With this SpERC outdoor use is covered as well. Additionally, water contact during use is not excluded.

For further information on the release factors please refer to FEICA's background document.

B.9.8.2. Exposure estimation

Table 31. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	1.28%		
Total tonnage used in adhesives/sealants at prof. sites	96	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use	96	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	5.28E-5	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0		**Low emission scenario** FEICA / EFCC SPERC 8f.1a.v2
	0.15		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.015		**Low emission scenario** FEICA / EFCC SPERC 8f.1a.v2
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scenario** FEICA / EFCC SPERC 8f.1a.v2
	0.005		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste taking into account all sites	0.04 – 0.25		FEICA / EFCC SPERC 8f.1a.v2
Estimated release to air taking into account all sites	0 – 14 400	kg per year	
Estimated release to wastewater taking into account all sites	1 440 – 4 800	kg per year	

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Input factor/assumption	Value	Unit	Comment
Estimated release to industrial soil taking into account all sites	0 - 480	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	3 840 – 24 000	kg per year	
Total release taking into account all sites	5 280 – 43 680	kg per year	

B.9.8.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.8.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.8.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 32**.

Table 32. Estimated indirect local exposure of human via the environment from professional use of adhesives/sealants in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	5.73E-8	1.92E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	2.24E-4	0.0002	
Daily dose through intake of fish	1.85E-5	6E-5	mg/kg bw/d
Fraction of total dose through intake of fish	7.23E-2	0.0708	
Daily dose through intake of leaf crops	3.78E-7	6.50E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0015	0.0074	
Daily dose through intake of root crops	2.35E-4	7.88E-4	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9184	0.9010	
Daily dose through intake of meat	1.23E-6	1.13E-5	mg/kg bw/d
Fraction of total dose through intake of meat	0.0048	0.0129	
Daily dose through intake of milk	7.22E-7	6.65E-6	mg/kg bw/d
Fraction of total dose through intake of milk	0.0028	0.0076	
Local total daily intake of humans	2.56E-4	8.75E-4	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.97E-7	3.38E-6	mg/m^3
Man via environment - oral	2.56E-4	8.74E-4	mg/kg bw/d

B.9.8.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 33**.

Table 33. Estimated environmental local exposure from professional use of adhesives/sealants in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$\text{PEClocal}_{\text{freshwater}}$	2.17E-6	7.25E-6	mg/L
$\text{PEClocal}_{\text{freshwater sediment}}$	0.069	0.229	mg/kg dw
$\text{PEClocal}_{\text{marinewater}}$	2.19E-7	7.5E-7	mg/L
$\text{PEClocal}_{\text{marinewater sediment}}$	6.93E-3	0.024	mg/kg dw
$\text{PEClocal}_{\text{STP}}$	2.99E-5	9.97E-5	mg/L
$\text{PEClocal}_{\text{air}}$	1.97E-7	3.38E-6	mg/m^3
$\text{PEClocal}_{\text{agricultural soil}}$	0.013	0.043	mg/kg dw
$\text{PEClocal}_{\text{predators' prey (freshwater)}}$	0.06	0.201.	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (marine water)}}$	6.13E-3	0.021	mg/kg ww
$\text{PEClocal}_{\text{top predators' prey (marine water)}}$	0.19	0.073	mg/kg ww
$\text{PEClocal}_{\text{predators' prey (terrestrial)}}$	0.036	0.122	mg/kg ww

B.9.8.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in adhesives/sealants is carried out collectively for all uses as indicated below:

- Formulation of adhesives and sealants,
- Use of adhesives and sealants at industrial sites,
- Use of adhesives and sealants by professionals, and
- Service life of articles produced from use as plasticiser.

Please refer to Chapter B.9.9.4.

B.9.9. Use 7: Service life of articles produced from use as plasticiser

B.9.9.1. General information

Terphenyl, hydrogenated is used as plasticiser in adhesives and sealants. In the public consultation it was stated by one respondent who represents over 3000 companies that Terphenyl, hydrogenated is used by aerospace and defence industries since it is a constituent of sealant/adhesive formulations. However, no specific information on the releases to the environment of articles produced from use of adhesives and sealants containing Terphenyl, hydrogenated is available. Nevertheless, results obtained in a leaching/migration estimation conducted by FABES (2021) are available. Please also refer to Chapter 9.9.2.4.

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B.9.9.2. Exposure estimation

Table 34. Assumptions for Exposure Estimation

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	6.24%		
Total tonnage used in articles	480	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use of article	480	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	2.64E-4	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	n.a.		**Low emission scenario**
	0.0005		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	n.a.		**Low emission scenario**
	0.032		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	n.a.		**Low emission scenario**
	0.032		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste taking into account all sites	n.a.		
Estimated release to air taking into account all sites	240	kg per year	
Estimated release to wastewater taking into account all sites	15 360	Kg per year	
Estimated release to industrial soil taking into account all sites	15 360	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	n.a.	kg per year	
Total release taking into account all sites	30 960	kg per year	

B.9.9.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.9.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.9.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the table below. Estimated indirect local exposure of human via the environment from service life of articles produced from use as plasticiser in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	n.a.	6.12E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	2E-4	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0724	
Daily dose through intake of leaf crops	n.a.	8.76E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0032	
Daily dose through intake of root crops	n.a.	2.51E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9129	
Daily dose through intake of meat	n.a.	1.96E-5	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0071	
Daily dose through intake of milk	n.a.	1.15E-5	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0042	
Local total daily intake of humans	n.a.	2.75E-3	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	4.56E-6	mg/m^3
Man via environment - oral	n.a.	2.75E-3	mg/kg bw/d

B.9.9.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 35**.

Table 35. Estimated environmental local exposure from service life of articles produced from use as plasticiser in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{freshwater}$	n.a.	2.32E-5	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	0.735	mg/kg dw
$PEClocal_{marinewater}$	n.a.	2.36E-6	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	0.075	mg/kg dw
$PEClocal_{STP}$	n.a.	3.19E-4	mg/L

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{air}$	n.a.	4.56E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	0.136	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	n.a.	0.646	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	n.a.	0.067	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	n.a.	0.217	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	n.a.	0.39	mg/kg ww

B.9.9.3. Migration modelling

In addition to experimental methods, an alternative tool based on theoretical migration estimations can be applicable for verifying the leaching/migration of substances from specific matrixes. The EU introduced this option to use generally recognised diffusion models as a novel compliance and quality assurance tool for assessing food contact compliance[28].

Migration is a global term to describe a net mass transfer of a chemical substance from one material (e.g., plastic packaging) into another medium (e.g., food, water, air). Migration includes several macroscopic mass transfer mechanisms, such as:

- Mass diffusion in and through the different (polymer) materials as well as the liquid or gas phases separating the primary source from the target medium.
- Desorption/sorption at the interface between each crossed medium. When it involves fluid phases, migration may also cover an additional transport or mixing effect by advection.

Migration modelling is an abstract process aiming at calculating the maximum number of substances which might be transferred to the medium in contact, with various simplifications and assumptions. It is important to note that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms; instead, the objective is to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles.

Migration Scenario:

Estimation of Migration of Terphenyl, hydrogenated from a special polysulfide sealant (FABES, 2021)[29]

- Report No.: 7946-21
- Completion Date: 7.9.2021
- Number of Pages: 17

In this report the migration of Terphenyl, hydrogenated from a sample plate made of polysulfide sealant into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach.

The polysulfide sealant is used in the aerospace industry as integral fuel tank and aircraft body sealant. The two-component polysulfide sealant is obtained by the mixing of a base component and a catalyst. Initially Terphenyl, hydrogenated is part of the catalyst component (30 to 45% w/w), but in the freshly mixed sealant (which is a thixotropic paste) Terphenyl,

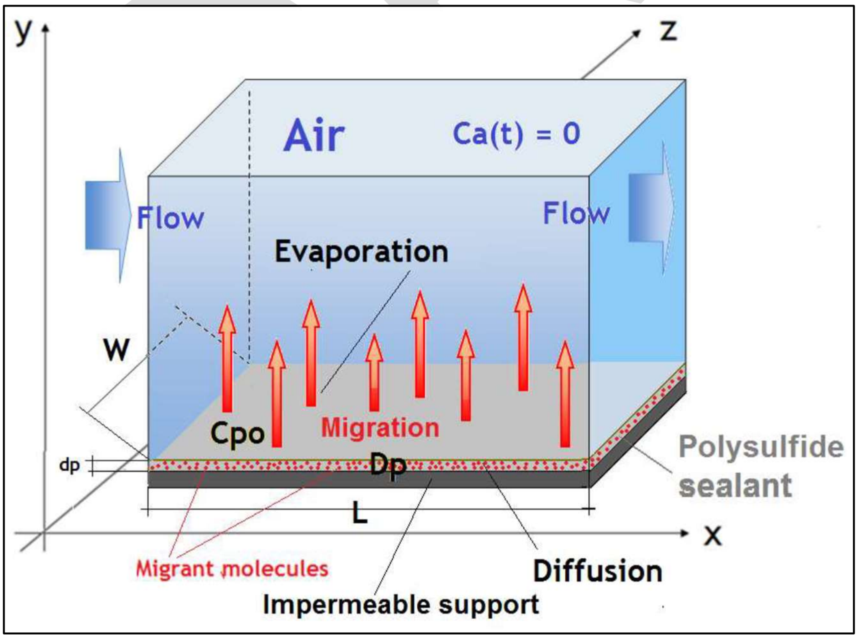
[28] JRC Publications Repository - Practical guidelines on the application of migration modelling for the estimation of specific migration (europa.eu)

[29] Fabes (2021): Estimation of Migration of hydrogenated Terphenyl from a special polysulfide sealant.-

hydrogenated is uniformly distributed. This is most likely also the case after several hours with the cured sealant. In principle one can assume that the molecules of Terphenyl, hydrogenated ("the migrant") are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the cured polysulfide sealant. Thus, the Terphenyl, hydrogenated molecules exhibit a certain mobility (diffusivity) in the network of the free-volumes of this polysulfide sealant. That means that in the presence of a Terphenyl, hydrogenated concentration gradient (which acts as a driving force) inside the cured polysulfide sealant, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the sealant is controlled mainly by the mobility (Dp) and the magnitude of the migrant concentration gradient inside the cured polysulfide sealant. It is well known that the service time of aircraft and aerospace structures may extend over several decades. During this time the temperature to which the cured sealant mass is exposed may range from low two digits sub-zero °C levels to high two digits positive ones. From basic physical-chemical principles it is logic to assume that Terphenyl, hydrogenated molecules, situated in the polysulfide sealant just underneath its "air-contact surface", which accumulate enough energy may leach from the sealant, evaporate, and diffuse into the air. The higher the temperature, T, the more energy is accumulated by the Terphenyl, hydrogenated molecules and consequently the more leaching from the sealant takes place. Once some part of the Terphenyl, hydrogenated molecules leave the "air-contact surface" of the polysulfide sealant, a migrant concentration gradient between this region and the "core" of the sealant results. This gradient determines the internal diffusion of Terphenyl, hydrogenated molecules from the "core" towards the "air-contact surface" of the sealant material. The whole process of Terphenyl, hydrogenated molecules diffusion in and leaching from the polysulfide sealant will be further called "the migration" of Terphenyl, hydrogenated from the sealant into air. Theoretically, this process lasts until mobile Terphenyl, hydrogenated molecules still exist in the polysulfide sealant.

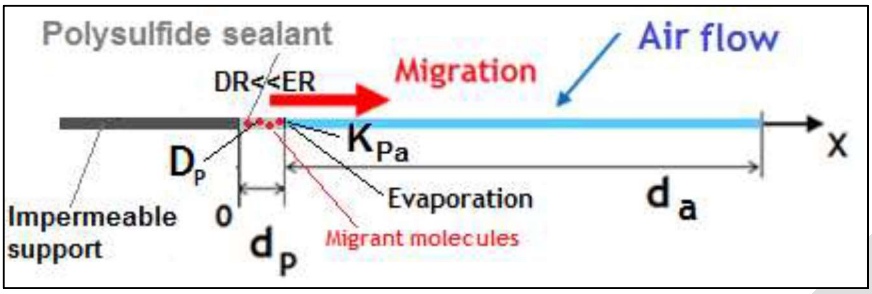
Schematically this process is presented in **Figure 16**. A migration of Terphenyl, hydrogenated cannot take place in the opposite direction because fuel tank and fuselage parts of an aerospace device can be considered as perfectly impermeable to any migrant molecule.

Figure 16. Schematic diagram of the migration of Terphenyl, hydrogenated from a plate made of a polysulfide sealant into air (Source: Fabes Report No. 7946-21, 2021, Fig. 1)



The calculation/estimation of a migration process has been conducted according to the previously described migration scenario and is illustrated in **Figure 17**.

Figure 17. 1D migration/leaching diagram from thin dry polysulfide sealant into an air flow (Source: Fabes Report No. 7946-21, 2021, Fig. 3)



The calculated time dependent increase of the migrated/leached Terphenyl, hydrogenated amount from the 100 cm² (10x10 cm) and 1.0 cm thick polysulfide sealant. Further calculations and input-parameters (incl. physical-chemical data of Terphenyl, hydrogenated and the coating) are available in the Fabes Report No. 7946-21, 2021. **Figure 18** is showing the calculated results for a service time of 10 and 20 years.

Figure 18. Time dependent amount of Terphenyl, hydrogenated migrated, at 20°C in 10 years, from the polysulfide sealant into a flow of air (Source: Fabes Report No. 7946-21, 2021, Fig. 4)

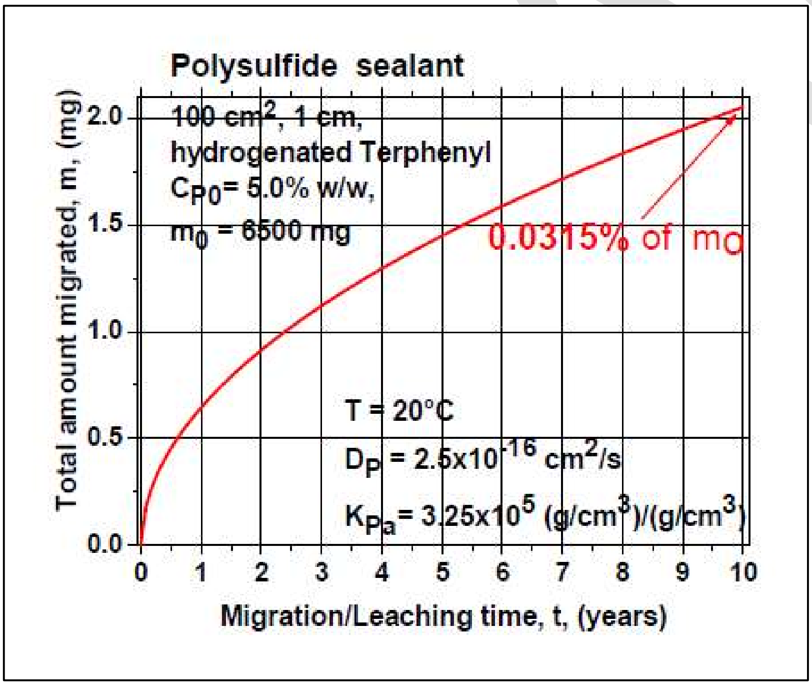
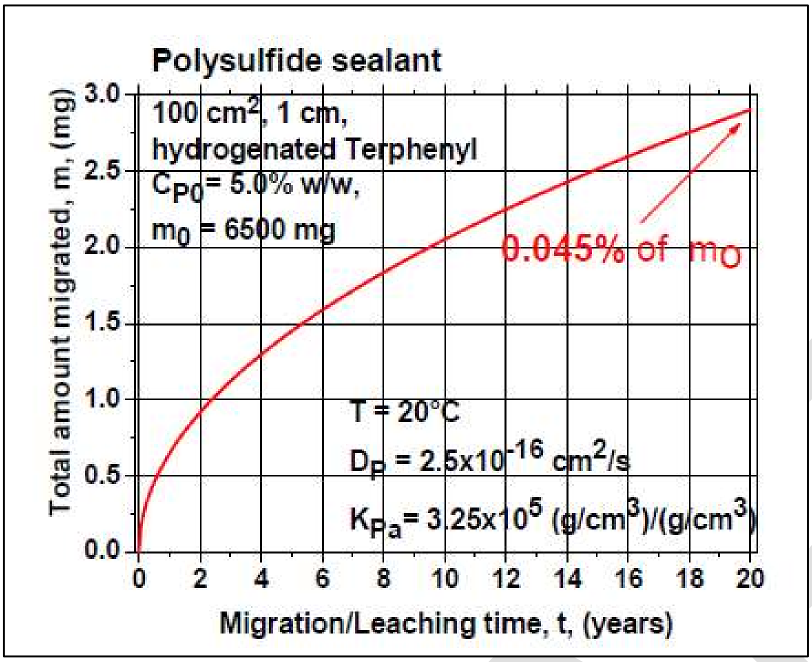


Figure 19. Time dependent amount of Terphenyl, hydrogenated migrated, at 20°C in 20 years, from the polysulfide sealant into a flow of air (Source: Fabes Report No. 7946-21, 2021, Fig. 5)



In conclusion, during a service life of 10 years ca. 0.031% of Terphenyl, hydrogenated used as a plasticizer in a polysulfide sealant for airplanes would migrate into the surrounding air. For a service life of 20 years, the loss of Terphenyl, hydrogenated would increase to ca. 0.045%.

The difference from the migration between Scenarios 1 and 2 are due to the differences in surface area and thicknesses between the coating and the sealant scenarios.

As discussed under **Annex A** (Manufacture and Use), the annual volume in the EU of aerospace sealants in 2018 is assumed to be 180 tonnes year (no volume increase/decrease over time was included). As a result, within a service life of 10 years potentially **0.5 tonnes** out of the 1.800 tonnes within the **10-years** range consumed could enter the environment. Considering a service life of **20 years** and 3 600 t of sealant used (180 tonnes year * 20 years), **1.6 tonnes** of Terphenyl, hydrogenated could potentially migrate from the polysulfide sealant into the environment. However, since airplanes do travel globally, the potential loss of Terphenyl, hydrogenated to the environment cannot be localized to the EU only. Anyhow, since non-EU planes will be using the same coatings and are in service in the EU too, the Dossier Submitter finds it reasonable to use these numbers as worst-case releases.

Migration Scenario:

Estimation of Migration of Terphenyl, hydrogenated from a plasticiser use in joint seals for underground cables (FABES, 2021)[30]

- Report No.: 8053-21
- Completion Date: 3.12.2021
- Number of Pages: 17

[30] Fabes (2021): Estimation of Migration of hydrogenated Terphenyl from a special Cable Joint made of a Polymer modified Bitumen Sealant.-

In this report the migration of Terphenyl, hydrogenated from a special cable joint sealant into the soil and groundwater surrounding a high voltage cable joint is estimated by means of a theoretical modelling approach.

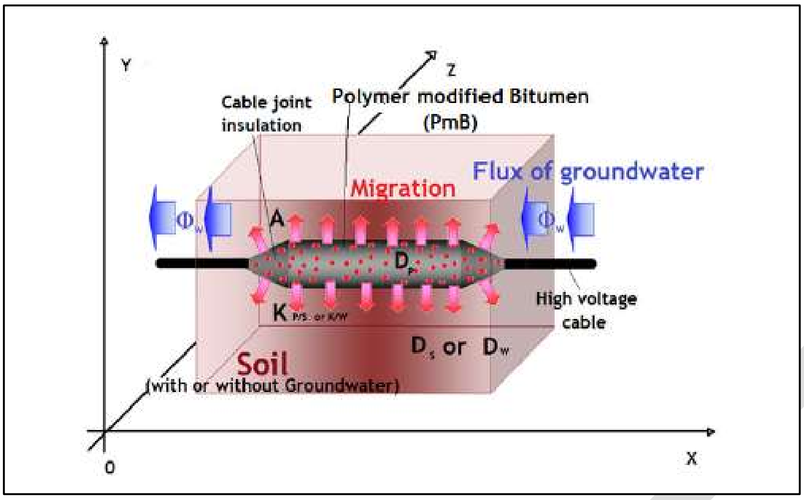
The polymer modified bitumen (PmB) is used as a sealant to insulate special high voltage cables. These cable joints are then buried in the soil with potential groundwater contact.

No further details about the chemical nature of the PmB materials were disclosed, but information is available that the polymer used is polyurethane (PU) and that the PmB material contains between 5 and 10% w/w of Terphenyl, hydrogenated.

In principle, it can be assumed that the molecules of Terphenyl, hydrogenated ("the migrant") are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the PmB material. Thus, the Terphenyl, hydrogenated molecules exhibit a given mobility (diffusivity) in the network of the free volumes of this sealant material. That means that in the presence of a Terphenyl, hydrogenated concentration gradient (which acts as a driving force) inside the PmB sealant, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the sealant is controlled mainly by the mobility (diffusion coefficient Dp) and the magnitude of the migrant concentration gradient inside the PmB material. Once the high voltage cables are buried in the soil this PmB coating/insulation will come into contact with the surrounding soil (which may or may not contain a given amount of water). Even more, in some cases the buried high voltage cables may come into contact with the groundwater. In such situations, from basic physical-chemical principles, it is logic to assume that Terphenyl, hydrogenated molecules, situated just underneath the contact surface of the PmB sealant and which accumulate enough energy may leach from the sealant and diffuse into the surrounding soil or ground water.

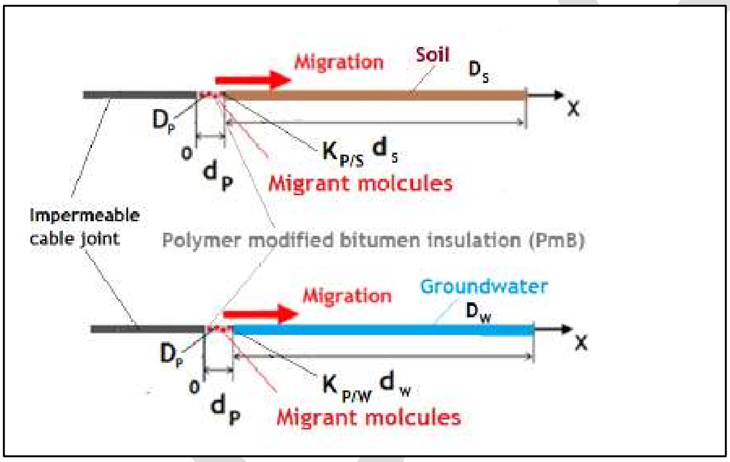
The higher the temperature T, the more energy is accumulated by the Terphenyl, hydrogenated molecules and consequently the more leaching from the PmB sealant takes place. Once some part of the Terphenyl, hydrogenated molecules "leave" the surface of the PmB coating/insulation a migrant concentration gradient between this region and the "core" of the sealant layer results. This gradient determines the internal diffusion of Terphenyl, hydrogenated molecules from the "core" towards the "contact surface" of the sealant layer. The whole process of Terphenyl, hydrogenated molecules diffusion in and leaching from the PmB material will be further called "the migration" of Terphenyl, hydrogenated from the sealant into the soil or groundwater. Theoretically, this process lasts until mobile Terphenyl, hydrogenated molecules still exist in the PmB material. Schematically this process is presented in **Figure 20**.

Figure 20. Schematic diagram of the migration of Terphenyl, hydrogenated from the insulation of a high voltage cable joint into surrounding soil (Source: Fabes Report No. 8053-21, 2021, Fig. 2)



The calculation/estimation of the migration process has been conducted according to the previously described migration scenarios and is illustrated in **Figure 21**.

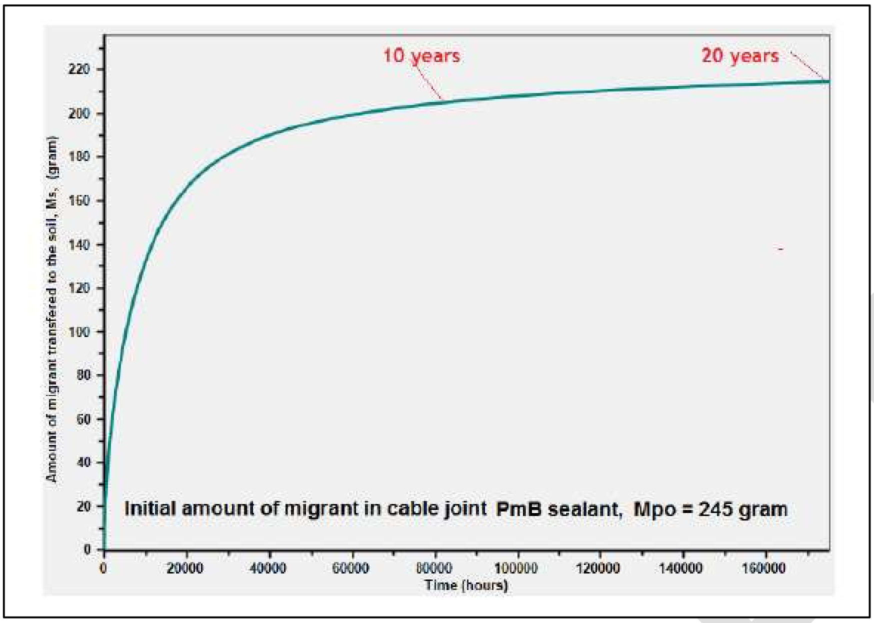
Figure 21. Schematic diagram Schematic presentation of the migration/leaching from a polymer modified bitumen (PmB) insulation of a special cable joint into the soil and groundwater (Source: Fabes Report No. 8053-21, 2021, Fig. 3)



In the migration modelling it was estimated that the total initial amount of Terphenyl, hydrogenated in the PMB sealant (m_{p0}) is 245 g, reflecting a cable joint with a length of 270 cm.

The calculated time dependent increase of the migrated/leached Terphenyl, hydrogenated amount from the biggest cable joint PmB sealant into a stagnant soil surrounding the cable joint in a 1 m radius is shown in **Figure 22**. Note, that M_{p0} is the total amount (in g) of Terphenyl, hydrogenated found initially in the PMB layer insulation the cable joint (at 10% w/w).

Figure 22. Time dependent amount of Terphenyl, hydrogenated migrated from the PMB insulation of the biggest cable joint into a 1 m thick stagnant soil layer surrounding the cable (Source: Fabes Report No. 8053-21, 2021, Fig. 4)



The temperature during the migration process was assumed to be 10°C and the migration rates were calculated for 10 and 20 years. According to the modelling, after 10 years > 80% and after 20 years > 85% of Terphenyl, hydrogenated migrated from the sealant into the soil. Assuming, that this application consumes 10 tonnes year within the EU, it can be concluded that ca. **80 tonnes** in total could be migrating within **10 years** into the environment, in **20 years** approximately **85 tonnes** could have been leached into the cable surrounding soil.

The migration of Terphenyl, hydrogenated into a flux of groundwater was modelled as well but the amounts of leached Terphenyl, hydrogenated into the groundwater were considerably lower compared to the migration into the soil, due to the very low water solubility of Terphenyl, hydrogenated.

B.9.9.4. Qualitative assessment

Introduction

The overall qualitative assessment of the use of Terphenyl, hydrogenated in adhesives/sealants is carried out collectively for all uses as indicated below:

- Formulation of adhesives and sealants,
- Use of adhesives and sealants at industrial sites,
- Use of adhesives and sealants by professionals, and
- Service life of articles produced from use as plasticiser.

General description

A small amount of Terphenyl, hydrogenated of approx. 6.5 % is used as plasticizer in adhesives and sealants. Adhesives and sealants are formulated and subsequently used by industry and professional workers. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material once the plasticizer is incorporated into/onto articles. Hence, the service life of the articles containing Terphenyl, hydrogenated need to be regarded as well.

The four uses indicated before are covered in this qualitative assessment.

During formulation, the Terphenyl, hydrogenated is mixed with other substance and repacked to be used as adhesives and sealants

During the industrial and professional use the adhesives and sealants are used in a wide variety of sectors, for example the aerospace industry. Hence, they are applied to various articles which are then used.

However, it has to be emphasized that very little specific information are available to the DS.

Environmental exposure

For all four uses assessed here only little or no specific information on the use and the release to the environment is available. In general, emissions to the environment are possible via releases to the air, water and soil. Further, waste generated during the use of Terphenyl, hydrogenated or articles containing Terphenyl. Hydrogenated needs to be taken into account.

Since no specific information is available to the DS the emissions are estimated based on the default release factors as given by the assigned ERCs. Further, FEICA / EFCC SpERCs were used for the refinement of the assessment due to the absence of more specific information.

For the refinement of the formulation scenario FEICA / EFCC SpERC 2.1a.v3 is used. It is indicated in the SpERC factsheet that the use is only conducted indoors and water contact is excluded. Further, the efficiency of the process is maximized and highly automated. To prevent and minimise releases to air closed or covered equipment is user and a waste air extraction system equipped with filters is place. Moreover, it is stated that equipment is cleaned with organic solvent and washings are collected and disposed of as solvent waste.

FEICA / EFCC SPERC 5.1a.v3 is used for the refinement of the industrial use. It is indicated in the SpERC factsheet that the use is only conducted indoors. In general, the industrial use of adhesives and sealants is regarded as highly automated. Further it is assumed that no wastewater is produced since the mixing of the hardener and base and the application are water-free processes.Equipment is cleaned with organic solvent and washings are collected and disposed of as external solvent waste. Mats used for scavenging overspray are disposed as external waste.

For the refinement of the professional use of adhesives and sealants containing Terphenyl, hydrogenated FEICA / EFCC SPERC 8f.1a.v2 was used. According to the SpERC factsheet, equipment is cleaned with organic solvent and washings are collected and disposed of as external solvent waste. If used by professionals the material is usually handled manually, the level of automation is low. In order to achieve an efficient use information of proper dosing is provided on the packaging.

All residues of products must be cured in the container before discarded and larger solvent washing volumes are collected and disposed of as solvent waste.

For further information on the SpERCs please refer to section B.9.6.1., B.9.7.1 and B.9.8.1.

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In addition, a migration study of Terphenyl, hydrogenated from a sample plate made of polysulfide sealant into the surrounding air/atmosphere is performed (please refer to Section B.9.9.3. for further information).

Moreover, a second migration study of Terphenyl, hydrogenated from a special cable joint sealant into the soil and groundwater surrounding a high voltage cable joint is estimated by means of a theoretical modelling approach is performed (please refer to Section B.9.9.3. for further information).

Table 36 Estimated releases for the uses assessed in this qualitative assessment

	Formulation	Ind. use in adhesives and sealants	Prof. use in adhesives and sealants	Service life of articles
Total tonnage used per year (t/y)	480	384	96	480
Estimated release to air (kg/y)	384 – 12 000	6 528 – 192 000	0 – 14 400	240
Estimated release to wastewater (kg/y)	96 – 9 600	0 – 192 000	1 440 – 4 800	15 360
Estimated release to industrial soil (kg/y)	0 – 48	0 – 3 840	0 – 480	15 360
Estimated amount to solid waste for disposal (kg/y)	960 – 14 400	0 – 23 040	3 840 - 24 000	n.a.
Total release (kg/y)	1 440 – 36 048	6 528 – 410 880	5 280 – 43 680	30 960
Percentage of used volume which is released (%)	0.3 – 7.51	1.7 - 107	5.5 – 45.5	6.45

For the two end-uses as well as the service life scenario high releases are expected in the high emission scenario using the ERC defaults.

Assuming that the low emission scenario is in general more realistic the formulation could be regarded as of minor concern since less than 1 % of the total tonnage used will be released. Further, it is expected that solvent waste is handled appropriately by certified waste handlers.

Regarding the industrial use in adhesives and sealants it needs to be pointed out that release of > 107 % for the industrial use and approx. 45 % for the professional use are not reasonable. In general, the release cannot be higher than the used tonnage. In the low emission scenario, the release is expected to be significantly lower: 1.7 and 5.5 % for the industrial and professional use, respectively. No specific information is available to the DS on how waste is handled. However, it is expected that solvent waste is handled appropriately by certified waste handlers when handled at industrial sites. This is also indicated by one respondent who represents > 3 000 companies participating in the public consultation. It is explained that all waste is discharged to hazardous waste which is to be collected and disposed of via licensed waste contractors. Further, the respondent confirmed the assumption of the

SpERC that there is no release to the wastewater since adhesive/sealant formulations are not water-miscible.

For professional use of sealants and adhesives containing it appears reasonable to assume that a release to the environment is inevitable although waste is possibly collected and disposed of as external solvent waste. Further, the manual handling and the low level of automation are prone to releases into the environment.

The release during the service life of articles where Terphenyl, hydrogenated is solely estimated using ERC 10a due to the lack of specific information. Although the release of approx. 6.5 % is not too high, it needs to be taken into account that no information regarding the amount of solid waste is available.

Further, two migration studies of Terphenyl, hydrogenated were performed. One study addresses the migration of Terphenyl, hydrogenated from a sample plate made of polysulfide sealant used by the aerospace industry into the surrounding air/atmosphere. In the study it was estimated that 0.031 % of Terphenyl, hydrogenated will be released into the surrounding air/atmosphere in 10 years. Over 20 years in service 0.045 % is estimated to be released into the surrounding air/atmosphere. Assuming that all adhesive/sealant containing Terphenyl, hydrogenated would be used by the aerospace industry a release to air of 150 t/y and 216 t/y are estimated for a service lifetime period of 10 and 20 years, respectively. Thereby, the value estimated for a service lifetime period of 20 years is very similar to the value estimated using the default value given by the ERC. In the second study the migration of Terphenyl, hydrogenated from a special cable joint sealant into the soil and groundwater surrounding a high voltage cable joint is estimate. In the study it was estimated that 80 % of Terphenyl, hydrogenated will be released over 10 years in service. Over 20 years in service 85 % is estimated to be released into the surrounding. Those values are significantly higher than the default value (0.05 %) as indicated by the ERC. A release of 80 % and 85 % would account for a release of 384 000 and 408 000 kg/y, respectively, solely to the soil compartment. Both values are higher than the total estimate release using the ERC. However, it needs to be emphasised that not all adhesives/sealants containing Terphenyl, hydrogenated will be used by as cable joint sealant.

At the end of the article service life the articles they will be disposed of. Thereby, all the Terphenyl, hydrogenated which is not expected to be released during the service life of the article will then be release over time. However, possibly some articles will also be incinerated. In this case the Terphenyl, hydrogenated will not be released. However, as indicated before specific information is not available so the waste life of articles with contain Terphenyl, hydrogenated is uncertain.

Conclusions

Regarding the formulation it is concluded that < 1 – 7.51 % of the used volume will possibly be released into the environment. However, it us assumed that it can be expected that solvent waste is handled appropriately by certified waste handlers which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional, cannot be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all waste would be handled and recycled accordingly emissions into the environment are expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable, whereas the professional end-use is more critical than the industrial end-use.

Regarding the service life of article no specific information is available to the DS. A constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

B.9.10. Use 8: Formulation of coatings/inks

B.9.10.1. General information

Terphenyl, hydrogenated is used as plasticiser in coatings and inks. No specific information on the releases to the environment of Terphenyl, hydrogenated from formulation of coatings/inks is available. However, a CEPE SpERC (CEPE SPERC 2.1c.v2) is applicable for the refinement of the default assumptions.

CEPE SpERC 2.1c.v2 describes the "Formulation of organic solvent borne coatings and inks – non volatiles"

Thereby, the whole process of formulation/manufacture of organic solvent borne liquid coatings and inks is covered.

Further, this SpERC only covers indoor use but water contact during use is not excluded. As indicated in the SpERC factsheet 225 emission days per year are assumed.

The release factors indicated are based on EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY – ESD - (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009.

B.9.10.2. Exposure estimation

Table 37. Assumptions for Exposure Estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	3.40%		
Total tonnage for formulation of coatings/inks	254	tonnes per year	
Number of emission days	100 - 225	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 CEPE SpERC 2.1c.v2
Daily amount of Terphenyl, hydrogenated formulated at a site (local scenario)	1.129 - 2.54	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	9.5E-5		**Low emission scnenario** SpERC 2.1c.v2
	0.025		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to Wastewater	5E-5		**Low emission scnenario** CEPE SpERC 2.1c.v2
	0.02		**High emission scenario**

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Input factor/assumption	Value	Unit	Comment
			Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scnenario** CEPE SpERC 2.1c.v2
	0.0001		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.01		CEPE SpERC 2.1c.v2
Estimated release to air	24.13 – 6 350	kg per year	
Estimated release to wastewater	12.70 – 5 080	kg per year	
Estimated release to industrial soil	0 – 25.40	kg per year	
Estimated amount to solid waste for disposal	2 540	kg per year	
Total release	36.83 – 13 995.4	kg per year	

B.9.10.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.10.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.10.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 38**.

Table 38. Estimated indirect local exposure of human via the environment from formulation of coatings/inks in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	4.08E-6	3.68E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	0.0002	0.0002	
Daily dose through intake of fish	7.62E-4	0.31	mg/kg bw/d
Fraction of total dose through intake of fish	0.0424	0.0197	
Daily dose through intake of leaf crops	3.53E-5	9.31E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0020	0.0006	

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Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of root crops	1.70E-2	1.51E+1	mg/kg bw/d
Fraction of total dose through intake of root crops	0.9466	0.9735	
Daily dose through intake of meat	9.87E-05	0.058	mg/kg bw/d
Fraction of total dose through intake of meat	0.0055	0.0037	
Daily dose through intake of milk	5.82E-05	0.034	mg/kg bw/d
Fraction of total dose through intake of milk	0.0032	0.0022	
Local total daily intake of humans	1.80E-2	1.55E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	1.84E-5	4.84E-3	mg/m^3
Man via environment - oral	0.018	15.49	mg/kg bw/d

B.9.10.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 39**.

Table 39. Estimated environmental local exposure from formulation of coatings/inks in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	1.45E-4	0.13	mg/L
$PEClocal_{freshwater\ sediment}$	4.574	4.12E+3	mg/kg dw
$PEClocal_{marinewater}$	1.45E-5	0.013	mg/L
$PEClocal_{marinewater\ sediment}$	0.457	411.6	mg/kg dw
$PEClocal_{STP}$	2.13E-3	1.919	mg/L
$PEClocal_{air}$	1.84E-5	4.84E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	0.908	817.1	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	2.318	927.3	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	0.232	92.73	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0.464	185.6	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	2.477	2.23E+3	mg/kg ww

B.9.10.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in coatings and inks is carried out collectively for all uses as indicated below:

- Formulation of coatings/inks,
- Direct use for industrial coatings/inks applications,
- Direct use for professional coatings/inks applications, and
- Service life of articles produced from use of coatings and inks.

Please refer to Chapter B.9.13.4.

B.9.11. Use 9: Direct use for industrial coatings and inks applications

B.9.11.1. General information

Terphenyl, hydrogenated is used as plasticiser in coatings and inks. Only little information on the releases to the environment of Terphenyl, hydrogenated from the industrial use of coatings and inks is available (received via the public consultation). For example, Terphenyl, hydrogenated is used by aerospace and defence industries since it is a constituent of some finish paint/top coat formulations. Nevertheless, a CEPE SpERC (CEPE SPERC 5.1a.v2) is applicable for the refinement of the default assumptions.

CEPE SpERC 5.1a.v2 describes the "Application - industrial - spraying - indoor use – non volatiles".

Thereby, the whole process of formulation/manufacture of organic solvent borne liquid coatings and inks is covered.

Further, this SpERC only covers indoor use (including spray application) as indicated by the title of the SpERC.

The release factors indicated for air and soil are based on the OECD ESD. The release factor for water is justified with the explanation that there is no emission to water during application and drying.

B.9.11.2. Exposure estimation

Table 40. Assumptions for Exposure Estimation

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7,471	tonnes per year	
Share of total volume	2.73%		
Total tonnage used in coatings/inks at ind. sites	204	tonnes per year	
Number of emission days	20 - 225	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 CEPE SPERC 5.1a.v2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	0.091 – 1.02	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.015		**Low emission scenario** CEPE SPERC 5.1a.v2
	0.5		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0		**Low emission scenario** CEPE SPERC 5.1a.v2
	0.5		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0		**Low emission scenario** CEPE SPERC 5.1a.v2

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Input factor/assumption	Value	Unit	Comment
	0.01		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.1 - 0.52		CEPE SPERC 5.1a.v2
Estimated release to air taking into account all sites	3 060 – 102 000	kg per year	
Estimated release to wastewater taking into account all sites	0 – 102 000	kg per year	
Estimated release to industrial soil taking into account all sites	0 – 2 040	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	20 400 – 106 080	kg per year	
Total release taking into account all sites	23 460 – 312 120	kg per year	

B.9.11.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.11.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.11.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the

Table 41.

Table 41. Estimated indirect local exposure of human via the environment from industrial coatings and inks applications in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	1.33E-8	3.39E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	8.98E-6	0,0004	
Daily dose through intake of fish	3.01E-8	8.097	mg/kg bw/d
Fraction of total dose through intake of fish	2.03E-5	0.9931	
Daily dose through intake of leaf crops	4.49E-4	0.015	mg/kg bw/d

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Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Fraction of total dose through intake of leaf crops	0.3032	0.0018	
Daily dose through intake of root crops	5.47E-5	1.84E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0369	0.0002	
Daily dose through intake of meat	6.15E-4	0.023	mg/kg bw/d
Fraction of total dose through intake of meat	0.4153	0.0028	
Daily dose through intake of milk	3.62E-4	0.013	mg/kg bw/d
Fraction of total dose through intake of milk	0.2445	0.0016	
Local total daily intake of humans	1.48E-3	8.15	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.34E-4	7.81E-3	mg/m^3
Man via environment - oral	1.48E-3	8.153	mg/kg bw/d

B.9.11.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the

Table 42.

Table 42. Estimated environmental local exposure from industrial coatings and inks applications in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	3.52E-9	17.29	mg/L
$PEClocal_{freshwater\ sediment}$	1.11E-4	5.47E5	mg/kg dw
$PEClocal_{marinewater}$	3.98E-9	1.73	mg/L
$PEClocal_{marinewater\ sediment}$	1.26E-4	5.47E+4	mg/kg dw
$PEClocal_{STP}$	0	0	mg/L
$PEClocal_{air}$	2.34E-4	7.81E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	2.9E-3	0.098	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	1.83E-4	2.46E+4	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	2.07E-4	2.46E+3	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	2.07E-3	4.93E+3	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	8.17E-3	1.467	mg/kg ww

B.9.11.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in coatings and inks is carried out collectively for all uses as indicated below:

- Formulation of coatings/inks,
- Direct use for industrial coatings/inks applications,

- Direct use for professional coatings/inks applications, and
- Service life of articles produced from use of coatings and inks.

Please refer to Chapter B.9.13.4.

B.9.12. Use 10: Direct use for professional coatings/inks applications

B.9.12.1. General information

Terphenyl, hydrogenated is used as plasticiser in coatings and inks. No specific information on the releases to the environment of Terphenyl, hydrogenated from the professional use of coatings/inks is available. However, a CEPE SpERC (CEPE SPERC 8f.3a.v2) is applicable for the refinement of the default assumptions. Thereby, the release to soil is higher using the SpERC than the default release factor as indicated in ECHA Guidance R.16.

CEPE SpERC 8f.3a.v2 describes the "Professional application of coatings and inks by spraying; Application - professional - spraying - outdoor use – non-volatile".

Thereby, the whole process of application of organic solvent borne and water borne liquid coatings and inks by professional users by spraying is covered. In exact this includes: Application of coatings by spray, cleaning of equipment and waste management of coatings.

Since this SpERC is applicable to ERC 8f outdoor use (including spray application) is covered as well as the water contact during use.

The release factors indicated for air is based on the OECD ESD. The release factor for water is justified with the explanation that during application of coatings outdoors a proportion of the applied coating can be deposited into water. Regarding the release to soil it is indicated that during application of coating outdoors a proportion of the applied coating (solid phase) can be deposited on the soil below the area being painted.

B.9.12.2. Exposure estimation

Table 43. Assumptions for Exposure Estimation

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7,471	tonnes per year	
Share of total volume	0.68%		
Total tonnage used in adhesives/sealants at prof. sites	50	tonnes per year	
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use	50	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	2.75E-5	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	0		**Low emission scenario** CEPE SPERC 8f.3a.v2

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Input factor/assumption	**Value**	**Unit**	**Comment**
	0.15		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.02		**Low emission scenario** CEPE SPERC 8f.3a.v2
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.02		**Low emission scenario** CEPE SPERC 8f.3a.v2
	0.005		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.09 - 0.3		CEPE SPERC 8f.3a.v2
Estimated release to air taking into account all sites	0 – 7 500	kg per year	
Estimated release to wastewater taking into account all sites	1 020 – 2 500	kg per year	
Estimated release to industrial soil taking into account all sites	250 – 1 000	kg per year	It needs to be noted that the lower estimated release to soil is derived based on the ERC defaults, not the assigned SpERC. Since the default of the ERC is considered for the high emission scenario the associated estimated release is also considered for the upper limit of the total release.
Estimated amount to solid waste for disposal taking into account all sites	4 500 - 15 000	kg per year	
Total release taking into account all sites	6 500 – 25 250	kg per year	It needs to be noted that the lower estimated release to soil is derived based on the ERC defaults, not the assigned SpERC. Since the default of the ERC is considered for the high emission scenario the associated estimated release is also considered for the upper limit of the total release.

B.9.12.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

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B.9.12.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.12.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 44**.

Table 44. Estimated indirect local exposure of human via the environment from professional coatings and inks applications in the EU

Route of exposure of humans via the environment	**Lower estimate**	**Upper estimate**	**Unit**
Daily dose through intake of drinking water	3,99E-08	1,00E-07	mg/kg bw/d
Fraction of total dose through intake of drinking water	2,22E-04	2,19E-04	
Daily dose through intake of fish	1,30E-05	3,24E-05	mg/kg bw/d
Fraction of total dose through intake of fish	0,0724	0,0710	
Daily dose through intake of leaf crops	5,64E-07	3,38E-06	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0,0031	0,0074	
Daily dose through intake of root crops	1,64E-04	4,11E-04	mg/kg bw/d
Fraction of total dose through intake of root crops	0,9130	0,9009	
Daily dose through intake of meat	1,27E-06	5,87E-06	mg/kg bw/d
Fraction of total dose through intake of meat	0,0071	0,0129	
Daily dose through intake of milk	7,46E-07	3,46E-06	mg/kg bw/d
Fraction of total dose through intake of milk	0,0042	0,0076	
Local total daily intake of humans	1,80E-04	4,56E-04	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2,87E-07	1,72E-06	mg/m^3
Man via environment - oral	1,80E-04	4,56E-04	mg/kg bw/d

B.9.12.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 45**.

Table 45. Estimated environmental local exposure from professional coatings and inks applications in the EU

Compartment	**Lower estimate**	**Upper estimate**	**Unit**
$PEClocal_{freshwater}$	1.52E-6	3.79E-6	mg/L

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater\ sediment}$	0.048	0.12	mg/kg dw
$PEClocal_{marinewater}$	1.54E-7	3.92E-7	mg/L
$PEClocal_{marinewater\ sediment}$	4.88E-3	0.012	mg/kg dw
$PEClocal_{STP}$	2.08E-5	5.21E-5	mg/L
$PEClocal_{air}$	2.87E-7	1.72E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	8.87E-3	0.022	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	0.042	0.105	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	4.35E-3	0.011	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	0.014	0.038	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	0.025	0.064	mg/kg ww

B.9.12.3. Qualitative assessment

The overall qualitative assessment of the use of Terphenyl, hydrogenated in coatings and inks is carried out collectively for all uses as indicated below:

- Formulation of coatings/inks,
- Direct use for industrial coatings/inks applications,
- Direct use for professional coatings/inks applications, and
- Service life of articles produced from use of coatings and inks.

Please refer to Chapter B.9.13.4.

B.9.13. Use 11: Service life of articles produced from use of coatings and inks

B.9.13.1. General information

Terphenyl, hydrogenated is used as plasticiser in coatings and inks. In the public consultation it was stated by one respondent who represents over 3000 companies that Terphenyl, hydrogenated is used by aerospace and defence industries since it is a constituent of coating formulations. However, no specific information on the releases to the environment of articles produced from use of coatings and inks containing Terphenyl, hydrogenated is available. However, results obtained in a leaching/migration estimation conducted by FABES (2021) are available. Please also refer to Chapter 9.13.2.4.

B.9.13.2. Exposure estimation

Table 46. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	3.40%		
Total tonnage used in articles	254	tonnes per year	

Input factor/assumption	Value	Unit	Comment
Share of volume used outdoor	100%		Worst-case assumption
Total tonnage – outdoor use of article	254	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	1.4E-4	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	n.a.		**Low emission scenario**
	0.0005		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	n.a.		**Low emission scenario**
	0.032		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	n.a.		**Low emission scenario**
	0.032		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air taking into account all sites	n.a. - 127	kg per year	
Estimated release to wastewater taking into account all sites	n.a. – 8 128	kg per year	
Estimated release to industrial soil taking into account all sites	n.a. - 8 128	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	n.a.	kg per year	
Total release taking into account all sites	16 383	kg per year	

B.9.13.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.13.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

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B 9.13.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 47**.

Table 47. Estimated indirect local exposure of human via the environment from service life of articles produced from use of coatings and inks in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	n.a.	3.24E-7	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	1.05E-4	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0721	
Daily dose through intake of leaf crops	n.a.	4.64E-6	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0032	
Daily dose through intake of root crops	n.a.	1.33E-3	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9132	
Daily dose through intake of meat	n.a.	1.04E-5	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0071	
Daily dose through intake of milk	n.a.	6.10E-6	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0042	
Local total daily intake of humans	n.a.	1.46E-3	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	2.41E-6	mg/m^3
Man via environment - oral	n.a.	1.46E-3	mg/kg bw/d

B.9.13.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 48**.

Table 48. Estimated environmental local exposure from service life of articles produced from use of coatings and inks in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	n.a.	1.23E-5	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	0.389	mg/kg dw
$PEClocal_{marinewater}$	n.a.	1.25E-6	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	0.04	mg/kg dw
$PEClocal_{STP}$	n.a.	1.69E-4	mg/L
$PEClocal_{air}$	n.a.	2.41E-6	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	0.072	mg/kg dw

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Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{predators' prey (freshwater)}$	n.a.	0.342	mg/kg ww
$PEClocal_{predators' prey (marine water)}$	n.a.	0.035	mg/kg ww
$PEClocal_{top predators' prey (marine water)}$	n.a.	0.115	mg/kg ww
$PEClocal_{predators' prey (terrestrial)}$	n.a.	0.206	mg/kg ww

B.9.13.3. Migration modelling

In addition to experimental methods, an alternative tool based on theoretical migration estimations can be applicable for verifying the leaching/migration of substances from specific matrixes. The EU introduced this option to use generally recognised diffusion models as a novel compliance and quality assurance tool for assessing food contact compliance[31].

Migration is a global term to describe a net mass transfer of a chemical substance from one material (e.g., plastic packaging) into another medium (e.g., food, water, air). Migration includes several macroscopic mass transfer mechanisms including:

- Mass diffusion in and through the different (polymer) materials as well as the liquid or gas phases separating the primary source from the target medium.
- Desorption/sorption at the interface between each crossed medium. When it involves fluid phases, migration may also cover an additional transport or mixing effect by advection.

Migration modelling is an abstract process aiming at calculating with various simplifications and assumptions the maximum amount of substances which might be transferred to the medium in contact. It is important to note that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms but to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles.

Migration Scenario:

Estimation of Leaching/Migration of Terphenyl, hydrogenated from a special epoxy top coating (Fabes, 2021)[32]:

- Report No.: 7945-21
- Completion Date: 3.9.2021
- Number of Pages: 17

In this report the leaching/migration of Terphenyl, hydrogenated from a special epoxy topcoat, used in the aerospace & defence industry, into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach.

The coating is used to protect metallic structures. It contains a certain amount of Terphenyl, hydrogenated and is a three component, water-borne, glossy epoxy-coating obtained by mixing a so-called base with a hardener/catalyst and using demineralised water as thinner. Initially Terphenyl, hydrogenated is part of the base component (5 to 10% w/w), but after the mixing

[31] JRC Publications Repository - Practical guidelines on the application of migration modelling for the estimation of specific migration (europa.eu)

[32] Fabes (2021): Estimation of Leaching/Migration of hydrogenated Terphenyl from a special epoxy top coating.-

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of the base with the hardener and thinner this substance is uniformly distributed in the topcoat. This is most likely also the case when the topcoat dries after several hours.

In principle, it can be assumed that the molecules of Terphenyl, hydrogenated ("the migrant") are most likely not firmly bound, trapped and cross linked (for example by strong covalent or ionic bounds) in the dry coating. Thus, the Terphenyl, hydrogenated molecules exhibit a certain mobility (diffusivity) in the network of the free volumes of the polymeric topcoat. That means that in the presence of a Terphenyl, hydrogenated concentration gradient (which acts as a driving force) inside the coating, the molecules of the migrant can diffuse/move towards regions with lower concentrations of this substance. The rate of this internal diffusion in the coating is controlled mainly by the mobility (diffusion coefficient - Dp) of the Terphenyl, hydrogenated molecules and the magnitude of the migrant concentration gradient inside the dry topcoat. It is well known that the service time of the metallic aerospace structures coated with this coating may extend over several decades. During this time the topcoat may be exposed to temperatures that may range from low, two digits sub-zero levels to high two digits positive levels. From basic physical-chemical principles it is logic to assume that Terphenyl, hydrogenated molecules, which are situated in the top-coating just underneath its surface in contact with the surrounding atmosphere (air) and accumulate enough energy, may leach from the coating, evaporate, and diffuse into the air. The higher the temperature (T), the more energy is accumulated by Terphenyl, hydrogenated molecules and consequently the more leaching from the coating takes place. Once some part of the Terphenyl, hydrogenated molecules leave the "air-contact surface" of the coating, a migrant concentration gradient between this region and the "core" of the paint layer results. This gradient determines the internal diffusion of Terphenyl, hydrogenated molecules from the "core" of the paint layer towards its "air-contact surface". The whole process of Terphenyl, hydrogenated molecules diffusion in and leaching from the topcoat will be further called "the migration" of Terphenyl, hydrogenated from the coating into air. Theoretically, this process lasts until mobile Terphenyl, hydrogenated molecules still exist in the topcoat. Schematically this process is presented in **Figure 23**. A migration/leaching process cannot take place in the opposite direction because the metals coated with the coating can be considered as perfectly impermeable to any migrant molecule.

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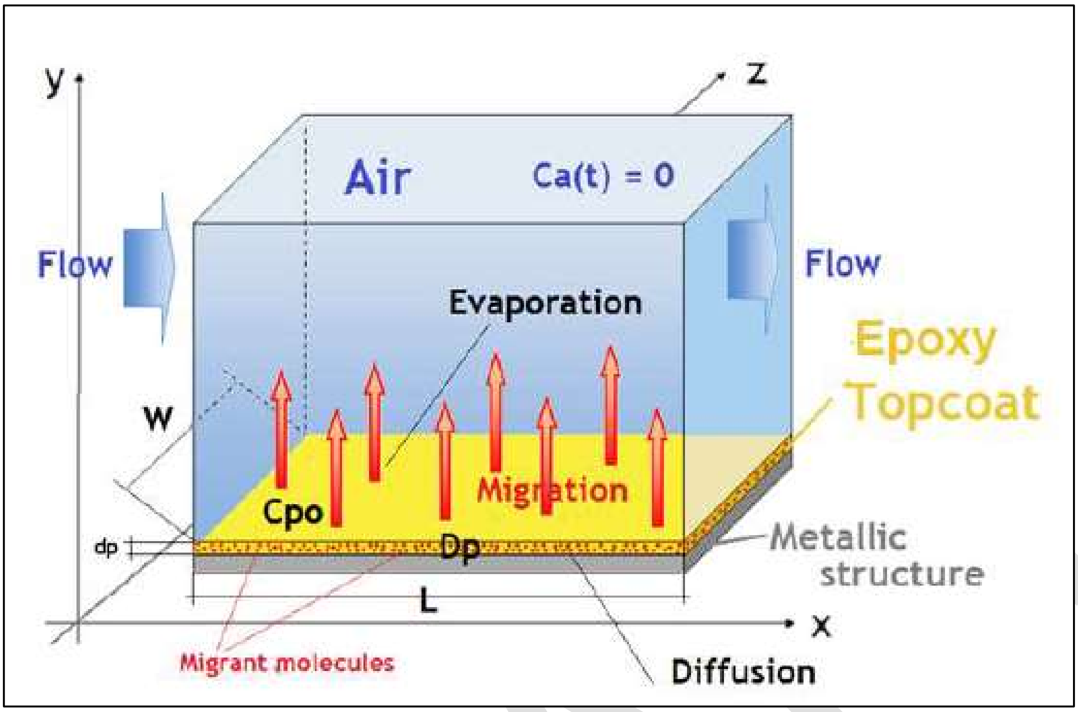
Figure 23. Schematic diagram of the migration of Terphenyl, hydrogenated from a topcoat layer into the surrounding atmosphere (flow of air) (Source: Fabes Report No. 7945-21, 2021, Fig. 1)



The rate of migration/leaching of Terphenyl, hydrogenated molecules from the topcoat into air depends, in principle, on the diffusion rate of Terphenyl, hydrogenated in the dry epoxy coating and on the evaporation rate of this migrant into air. Obviously, both processes are temperature dependent; the higher the temperature, the higher the diffusion rate and the evaporation rate.

Because in this migration scenario it is assumed that a flow of air always sweeps the painted metallic structure, an accumulation (till saturation) of Terphenyl, hydrogenated molecules in air never takes place. This means that the concentration of Terphenyl, hydrogenated in the air surrounding the sealant sample can be zero for any migration time. For the mathematical quantification of this migration process, it is important to know the relative magnitudes of the diffusion rate and evaporation rate processes. If the diffusion rate is significantly greater than the evaporation rate, this would mean that the migration process is predominantly "evaporation controlled". In case the evaporation rate is significantly greater than the diffusion rate, the migration process is "diffusion controlled". If both are similar, the migration process depends on both phenomena and it is "diffusion-evaporation controlled". To assess this problem for the migration scenario shown in **Figure 17**. it was the first necessary to specify the temperature/s during the migration process. As already mentioned, metallic structures of aerospace devices may be exposed (for shorter or longer periods) to severe sub-zero °C-temperatures but also to two digits positive °C temperatures.

It is well documented in the literature[33,34] that the diffusion/evaporation rate processes in discussion depend exponentially on the temperature.

Thus, Terphenyl, hydrogenated molecules in a coating may have diffusion and evaporation rates varying many orders of magnitude. Even more (because of the different activation energies) it might be that at low temperatures diffusion rate is greater than evaporation rate and at

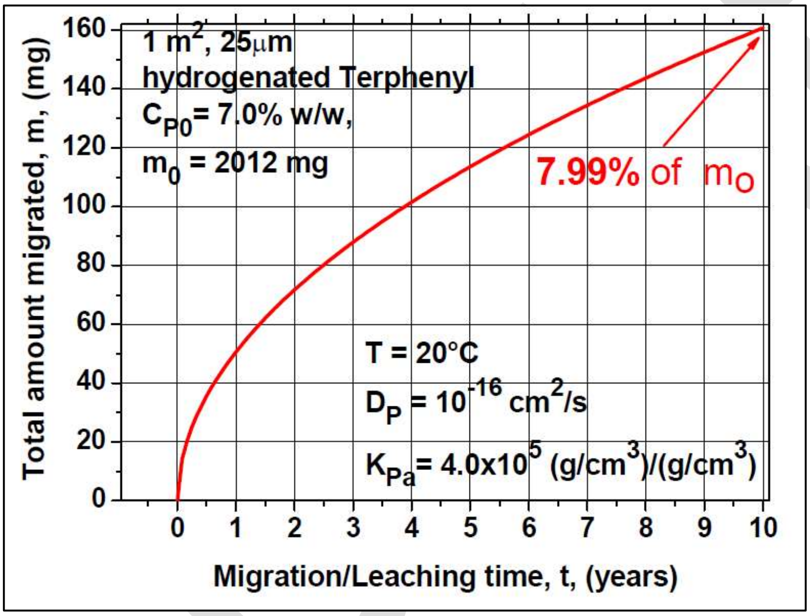
[33] 5.2C: Diffusion - Biology LibreTexts
[34] Fick's laws of diffusion - Wikipedia

high temperature the opposite situation is true. Therefore, a realistic assessment of when the migration of the Terphenyl, hydrogenated molecules from the topcoat is diffusion or evaporation controlled would require the knowledge of the "real time-temperature scenario" to which the aerospace device is exposed during its service time. But such information is difficult if not impossible to obtain. Because of that in a first approximation a very simple "time-temperature scenario", i.e., a thin layer of dry topcoat is kept at constant T=20°C for a service time of t = 10 or 20 years, in a steadily flowing flux of air. For this "time-temperature scenario" the migration was assessed. Further calculations and input-parameters (incl. physical-chemical data of Terphenyl, hydrogenated and the coating) are available in the Fabes Report No. 7945-21, 2021.

For the theoretical estimation of a migration process like the one discussed above, the information about the mobility (Dp) of the migrant molecules in the matrix of the topcoat and of the partitioning at equilibrium of the migrant at the boundary between this material and air (KPa) are indispensable and very important information. As already mentioned, in principle these coefficients can be determined experimentally but such a process might be challenging.

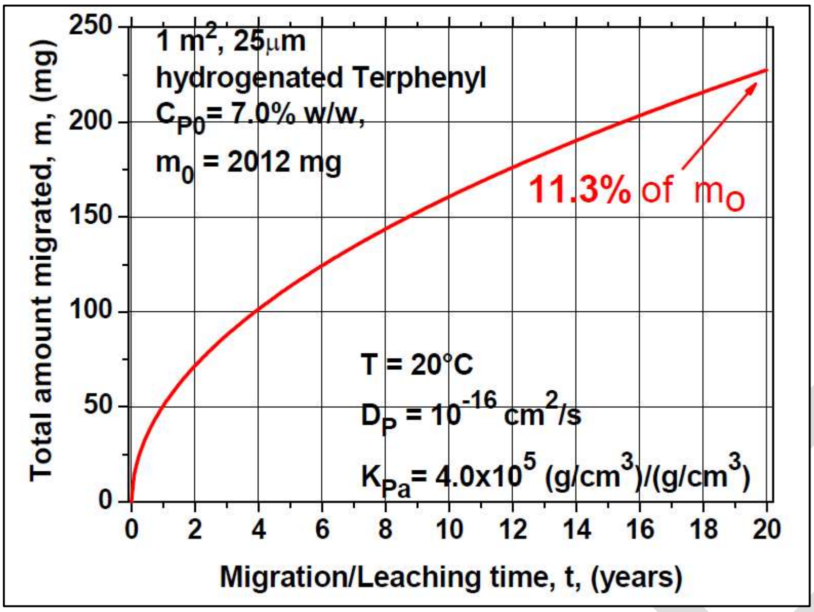
To estimate the amount of Terphenyl, hydrogenated migration at 20°C from the topcoat into air in 10 and 20 years, the software MIGRATEST®-Runner2020[35] was used. **Figure 24** and **Figure 25** show the calculated results for a service time of 10 and 20 years.

Figure 24. Time dependent amount of Terphenyl, hydrogenated migrated, at 20°C in 10 years, from the coating into a flow of air (Source: Fabes Report No. 7945-21, 2021, Fig. 4)



[35] Software | FABES Forschungs-GmbH (fabes-online.de)

Figure 25. Time dependent amount of Terphenyl, hydrogenated migrated, at 20°C in 20 years, from the coating into a flow of air (Source: Fabes Report No. 7945-21, 2021, Fig. 5)



In conclusion, during a service life of 10 years ca. 8% of Terphenyl, hydrogenated used as a plasticizer in a coating for airplanes would migrate into the surrounding air. For a service life of 20 years, the loss of Terphenyl, hydrogenated would increase to ca. 11%.

As discussed under **Annex A** (Manufacture and Use), the annual volume in the EU of aerospace coatings in 2018 is assumed to be 250 tonnes year (no volume increase over time considered). As a result, within a service life of 10 years potentially **200 tonnes** out of the 2.500 t within the **10-years** range consumed could enter the environment. Considering a service life of **20 years** and 5 000 tonnes of coating used (250 tonnes year * 20 years), **550 tonnes** of Terphenyl, hydrogenated could potentially migrate from the top-coating into the environment. However, since airplanes travel globally, the potential loss of Terphenyl, hydrogenated to the environment cannot be localized to the EU only. Anyhow, since non-EU planes will be using the same coatings and are in service in the EU too, the Dossier Submitter finds it reasonable to use these numbers as worst-case releases.

B.9.13.4. Qualitative assessment

Introduction

The overall qualitative assessment of the use of Terphenyl, hydrogenated in coatings and inks is carried out collectively for all uses as indicated below:

- Formulation of coatings/inks,
- Direct use for industrial coatings/inks applications,
- Direct use for professional coatings/inks applications, and
- Service life of articles produced from use of coatings and inks.

General description

A small amount of Terphenyl, hydrogenated of approx. 3.5 % is used as plasticizer in coatings and inks. Coatings and inks are formulated and subsequently used by industry and

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professional workers. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material once the plasticizer is incorporated into/onto articles. Hence, the service life of the articles containing Terphenyl, hydrogenated need to be regarded as well.

The four uses indicated before are covered in this qualitative assessment.

During formulation, the Terphenyl, hydrogenated is mixed with other substance and repacked to be used as coating or ink.

During the industrial and professional use the adhesives and sealants are used in a wide variety of sectors, for example the aerospace industry. Hence, they are applied to various articles which are then used.

However, it has to be emphasized that no specific information are available to the DS.

Environmental exposure

For all four uses assessed here no specific information on the use and the releases to the environment is available. In general, emissions to the environment are possible via releases to the air, water and soil. Further, waste generated during the use of Terphenyl, hydrogenated or articles containing Terphenyl, hydrogenated needs to be taken into account.

Since no specific information is available to the DS the emissions are estimated based on the default release factors as given by the assigned ERCs. Further, CEPE SpERCs were used for the refinement of the assessment due to the absence of more specific information.

For the refinement of the formulation scenario CEPE SpERC 2.1c.v2 is used. It is indicated in the SpERC factsheet that the use is only conducted indoors but water contact is not excluded. Further, the efficiency of the process is maximized and IED-abatement or a solvent management plan is in place to limit releases to the air. Moreover, process waste may be recycled or incinerated by waste disposal company

CEPE SpERC 5.1a.v2 is used for the refinement of the industrial use. It is indicated in the SpERC factsheet that the use is only conducted indoors but water contact is not excluded. Thereby, abatement techniques or a solvent management plan is in place limiting the release to water. Moreover, process waste may be recycled or incinerated by waste disposal company

For the refinement of the professional use of coatings and inks containing Terphenyl, hydrogenated CEPE SpERC 8f.3a.v2 was used. According to the SpERC factsheet it is assumed that during application of coatings outdoors a proportion of the applied coating can be deposited into water or on the soil below the area to be painted. Further it is assumed that waste water from equipment cleaning is discharged to standard municipal wastewater treatment plants. But process waste may be recycled or incinerated by local authority or waste disposal company.

For further information on the SpERCs please refer to section B.9.10.1., B.9.11.1 and B.9.12.1.

In addition, a leaching/migration study of Terphenyl, hydrogenated from a special epoxy topcoat, used in the aerospace & defence industry, into the surrounding air/atmosphere was estimated by means of a theoretical modelling approach is performed (please refer to Section B.9.13.3. for further information).

Table 49 Estimated releases for the uses assessed in this qualitative assessment

	Formulation	Ind. use in coatings and inks	Prof. use in coatings and inks	Service life of articles
Total tonnage used per year (t/y)	254	204	50	254
Estimated release to air (kg/y)	24.13 – 6 350	3 060 – 102 000	0 – 7 500	127
Estimated release to wastewater (kg/y)	12.7 – 5 080	0 – 120 000	1 000 – 2 500	8 128
Estimated release to industrial soil (kg/y)	0 – 25.4	0 – 2 040	250 - 1 000	8 128
Estimated amount to solid waste for disposal (kg/y)	2 540	20 400 – 106 080	4 500 – 15 000	n.a.
Total release (kg/y)	2 576 – 13 995.4	23 460 – 312 120	6 500 – 25 250	16 383
Percentage of used volume which is released (%)	1 – 5.51	11.5 - 153	13 – 50.5	6.45

For the two end-uses as well as the service life scenario high releases are expected in the refined, low emission scenario and of course in the scenario using the ERC defaults.

Assuming that the low emission scenario is in general more realistic the formulation could be regarded as of minor concern since only 1 % of the total tonnage used will be released. Further, it can be expected that process waste may be recycled or incinerated by waste disposal company which would result in an even lower release.

Regarding the industrial use in coatings and inks it needs to be pointed out that release of > 150 % is not reasonable since the release cannot be higher than the used tonnage. Even in the low emission scenario a release of 11.5 % of the total used tonnage is estimated. No specific information is available to the DS, but possibly process waste may be recycled or incinerated by waste disposal company which would result in lower releases. One respondent who represents > 3 000 companies participating in the public consultation explained that all waste is discharged to hazardous waste which is to be collected and disposed of via licensed waste contractors.

Looking at the professional use in coatings and inks a release of > 50 % is also assumed to be an overestimation. Nevertheless, it has to be acknowledged that a release is reasonable. Even in the low emission scenario a release of 13 % of the total used tonnage is estimated. Especially since outdoor use of coatings and inks containing Terphenyl, hydrogenated can't be denied due to the lack of information available to the DS. In this regard, it needs to be mentioned that the in the SpERC a release of 2 % to the soil is assumed which is four times higher than the default of the respective ERC (0.05 %).

The release during the service life of articles where Terphenyl, hydrogenated is present in the coating is solely estimated using ERC 10a due to the lack of specific information. Although the release of approx. 6.5 % is not too high, it needs to be taken into account that no information regarding the amount of solid waste is available. However, looking at the

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leaching/migration study of Terphenyl, hydrogenated from a special epoxy topcoat, used in the aerospace & defence industry which was performed the estimated releases will be higher. In the study it was estimated that 8 % of Terphenyl, hydrogenated will be released into the surrounding air/atmosphere in 10 years. Over 20 years in service 11 % is estimated to be released into the surrounding air/atmosphere. Those values are significantly higher than the default value (0.05 %) as indicated by the ERC. A release of 8 % and 11 % would account for a release of 20 320 and 27 940 kg/y, respectively, solely to the air compartment. Both values are higher than the total estimate release using the ERC. However, it needs to be emphasised that not all coatings containing Terphenyl, hydrogenated will be used by the aerospace and defence industry.

At the end of the service life of the articles they will be disposed of. Thereby, all the Terphenyl, hydrogenated which is not expected to be released during the service life of the article will then be release over time. Possibly some of the articles will be incinerated. In this case the Terphenyl, hydrogenated will not be released. However, as indicated before specific information is not available so the waste life of articles coated with a coating containing Terphenyl, hydrogenated is uncertain.

Conclusions

Regarding the formulation it is concluded that about 1 – 5.5 % of the used volume will possibly be released into the environment. However, it is assumed that it can be expected that process waste may be recycled or incinerated by waste disposal company which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional cannot be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all the process waste would be recycled or incinerated the assumed emissions into the environment can still be expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable.

Regarding the service life of article no specific information are available to the DS. However, a constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles coated with a coating containing Terphenyl, hydrogenated is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

B.9.14. Use 13: Formulation - use as additive in plastic applications

B.9.14.1. General information

The "Formulation - use as additive in plastic applications" is already sufficiently covered by the following uses:

- Formulation of coatings/inks
- Formulation of adhesives and sealants

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.14.2. Exposure estimation

The "Formulation - use as additive in plastic applications" is already sufficiently covered by the following uses:

- Formulation of coatings/inks
- Formulation of adhesives and sealants

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.15. Use 14: Use as additive in plastic application

B.9.15.1. General information

The "Use as additive in plastic application" is already sufficiently covered by the following uses:

- Direct use for industrial coatings/inks applications
- Use of adhesives and sealants at industrial sites

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.15.2. Exposure estimation

The "Use as additive in plastic application" is already sufficiently covered by the following uses:

- Direct use for industrial coatings/inks applications
- Use of adhesives and sealants at industrial sites

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

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Please refer to the respective sections for further information.

B.9.16. Use 15: Service life of plastics

B.9.16.1. General information

The "Service life of plastics" is already sufficiently covered by the following uses:

- Service life of articles produced from use of coatings and inks
- Service life of articles produced from use as plasticiser

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.16.2. Exposure estimation

The "Service life of plastics" is already sufficiently covered by the following uses:

- Service life of articles produced from use of coatings and inks
- Service life of articles produced from use as plasticiser

Hence there is no need to assess the "Use as additive in plastic application" in a separate use since it is assumed to be sufficiently covered by the more specific uses indicated above.

Please refer to the respective sections for further information.

B.9.17. Use 15: Formulation, transfer and repackaging of substances in preparations and mixtures

B.9.17.1. General information

A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. The formulation, transfer and repacking of Terphenyl, hydrogenated used as solvent/ process medium by the industry or as laboratory chemical by professional is covered by this scenario. No specific information on the releases to the environment is available.

B.9.17.2. Exposure estimation

Table 50. Assumptions for Exposure Estimations

Input factor/assumption	**Value**	**Unit**	**Comment**
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.49%		

Input factor/assumption	Value	Unit	Comment
Total tonnage used for solvent/processing aid and laboratory chemical formulations	36.5	tonnes per year	
Number of emission days	10	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2
Daily amount of Terphenyl, hydrogenated formulated at a site (local scenario)	3.65	tonnes per day	Estimate – assumes all of the tonnage is formulated at one site as a worst case
Fraction released to air	n.a.		**Low emission scenario**
	0.025		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	n.a.		**Low emission scenario**
	0.02		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	n.a.		**Low emission scenario**
	0.0001		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air	n.a. - 912.5	kg per year	
Estimated release to wastewater	n.a. - 730	kg per year	
Estimated release to industrial soil	n.a. - 3.65	kg per year	
Estimated amount to solid waste for disposal	n.a.	kg per year	
Total release	1 646	kg per year	

B.9.17.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.17.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.17.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 51**.

Table 51. Estimated indirect local exposure of human via the environment from formulation, transfer and repackaging of substances in preparations and mixtures in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	n.a.	5.28E-3	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	0.04	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0020	
Daily dose through intake of leaf crops	n.a.	1.37E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0001	
Daily dose through intake of root crops	n.a.	2.17E+1	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9928	
Daily dose through intake of meat	n.a.	0.067	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0031	
Daily dose through intake of milk	n.a.	0.039	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0018	
Local total daily intake of humans	n.a.	2.18E+1	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	6.95E-4	mg/m^3
Man via environment - oral	n.a.	21.83	mg/kg bw/d

B.9.17.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 52**.

Table 52. Estimated environmental local exposure from formulation, transfer and repackaging of substances in preparations and mixtures in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	n.a.	0.187	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	5.91E+3	mg/kg dw
$PEClocal_{marinewater}$	n.a.	0.019	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	591.4	mg/kg dw
$PEClocal_{STP}$	n.a.	2.757	mg/L
$PEClocal_{air}$	n.a.	6.95E-4	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	1.17E+3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	n.a.	133.2	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	n.a.	13.32	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	n.a.	26.68	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	n.a.	3.2E3	mg/kg ww

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B.9.17.3. Qualitative assessment

A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. Those two scenarios as well as the corresponding formulation are assessed collectively.

Hence, the overall qualitative assessment of is carried out collectively for the uses as indicated below:

- Formulation, transfer and repackaging of substances in preparations and mixtures,
- Use as solvent/process medium, and
- Use as laboratory chemical by professionals.

Please refer to Chapter B.9.19.3.

B.9.18. Use 16: Use as solvent/process medium

B.9.18.1. General information

A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry. No specific information on the releases to the environment is available. However, an ESVOC SpERC (ESVOC SPERC 4.1.z.v2) is applicable for the refinement of the default assumptions.

ESVOC SpERC 4.1.z.v2 describes the "Use as a processing aid and/or an extraction solvent".

Thereby, the use of a substance as a process chemical or extraction agent is covered. In exact this includes recycling/ recovery, material transfers, storage, maintenance and loading (including marine vessel/barge, road/rail car and bulk container), sampling and associated laboratory activities.

The SpERC only covers indoor use but water contact is not excluded.

According to the SpERC factsheet the release factors for air has been adopted from a published source that documents the worst-case estimates of air emissions based on the expert judgement of environmental scientists from the Dutch National Institute for Public Health and the Environment (RIVM) (European Commission (2003). European Commission Technical Guidance Document on Risk Assessment (EUTGD), Report EUR 20418 EN/2, Appendix 1, Table A1.1, Brussels, Belgium).

The release factor to water is based on "CONCAWE (2012). Trends in oil discharged with aqueous effluents from oil refineries in Europe. Report No. 6/12. Brussels, Belgium". Thereby, the approach used to assign this value is largely qualitative in nature and takes into consideration both the physical properties of the substance and the magnitude of wastewater production at representative production sites. This release factor has been conservatively calculated using water solubility information together with survey results of wastewater effluent volume per tonne of capacity at European oil refineries.

Regarding the release factor to soil the SpERC factsheet states that the value has been adopted from an authoritative literature source that documents the release factors for each environmental release category (ERC). The preceding value corresponds to the default release factor for substance manufacturing (ERC 1) (ECHA (2016). Guidance on Information Requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment Version 3.0. Appendix A.16-1. Helsinki, Finland).

B.9.18.2. Exposure estimation

Table 53. Assumptions for Exposure Estimations

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.47%		
Total tonnage used as solvent/process medium at ind. sites	35	tonnes per year	
Number of emission days	20 - 300	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2 ESVOC SPERC 4.1.v2
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	0.012 - 0.175	tonnes per day	Estimate – assumes 10% of the total use occurs at a large site
Fraction released to air	0.00001		**Low emission scenario** ESVOC SPERC 4.1.z.v2
	1		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	0.00001		**Low emission scenario** ESVOC SPERC 4.1.z.v2
	1		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	0.0001		**Low emission scenario** ESVOC SPERC 4.1.z.v2
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	0.05		ESVOC SPERC 4.1.v2
Estimated release to air	0.4 – 35 000	kg per year	
Estimated release to wastewater	0.4 – 35 000	kg per year	
Estimated release to industrial soil	3.5 – 1 750	kg per year	
Estimated amount to solid waste for disposal	1 750	kg per year	
Total release	1 754 – 73 500	kg per year	

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B.9.18.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.18.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.18.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the **Table 54**.

Table 54. Estimated indirect local exposure of human via the environment from use as solvent/process medium in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	8.79E-10	1.30E-2	mg/kg bw/d
Fraction of total dose through intake of drinking water	3.86E-04	0.0002	
Daily dose through intake of fish	2.10E-06	2E-1	mg/kg bw/d
Fraction of total dose through intake of fish	9.22E-01	0.0040	
Daily dose through intake of leaf crops	5.27E-08	5.22E-3	mg/kg bw/d
Fraction of total dose through intake of leaf crops	0.0231	0.0001	
Daily dose through intake of root crops	7.68E-09	5.20E+01	mg/kg bw/d
Fraction of total dose through intake of root crops	0.0034	0.9907	
Daily dose through intake of meat	7.28E-08	0.163	mg/kg bw/d
Fraction of total dose through intake of meat	0.0320	0.0031	
Daily dose through intake of milk	4.29E-08	0.096	mg/kg bw/d
Fraction of total dose through intake of milk	0.0188	0.0018	
Local total daily intake of humans	2.28E-06	5.24E+01	mg/kg bw/d
Man via environment - inhalation (systemic effects)	2.75E-8	2.68E-3	mg/m^3
Man via environment – oral	2.28E-6	52.44	mg/kg bw/d

B.9.18.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 55**.

Table 55. Estimated environmental local exposure from use as solvent/process medium in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	3.08E-7	0.448	mg/L
$PEClocal_{freshwater\ sediment}$	9.74E-3	1.42E-4	mg/kg dw
$PEClocal_{marinewater}$	3.08E-8	0.045	mg/L
$PEClocal_{marinewater\ sediment}$	9.74E-4	1.42E3	mg/kg dw

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{STP}$	4.53E-6	6.61	mg/L
$PEClocal_{air}$	2.65E-8	2.68E-3	mg/m^3
$PEClocal_{agricultural\ soil}$	4.08E-7	2.81E+3	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	6.41E-3	640.4	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	6.42E-4	64.06	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	1.31E-3	129.6	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	5.31E-6	7.68E+3	mg/kg ww

B.9.18.3. Qualitative assessment

A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. Those two scenarios as well as the corresponding formulation are assessed collectively.

Hence, the overall qualitative assessment of is carried out collectively for the uses as indicated below:

- Formulation, transfer and repackaging of substances in preparations and mixtures,
- Use as solvent/process medium, and
- Use as laboratory chemical by professionals.

Please refer to Chapter B.9.19.3.

B.9.19. Use 17: Use as laboratory chemical by professionals

B.9.19.1. General information

A very small amount of Terphenyl, hydrogenated is used as laboratory chemical by professional. Only little information on the releases to the environment is available.

B.9.19.2. Exposure estimation

Table 56. Assumptions for Exposure Estimation.

Input factor/assumption	Value	Unit	Comment
Total volume used in the EU	7 471	tonnes per year	
Share of total volume	0.02%		
Total tonnage used as laboratory chemical at prof. sites	1.5	tonnes per year	
Share of volume used outdoor	0		Reasonable worst-case assumption
Total tonnage – outdoor use	0	tonnes per year	
Number of emission days	365	days per year	Default from ECHA Guidance R.16 (2016), please refer to Table R.16-2

Input factor/assumption	Value	Unit	Comment
Daily amount of Terphenyl, hydrogenated used at a site (local scenario)	8.25E-7	tonnes per day	Estimated using ECHA Guidance R.16 (2016)
Fraction released to air	n.a.		**Low emission scenario**
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to wastewater	n.a.		**Low emission scenario**
	0.05		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to soil	n.a.		**Low emission scenario**
	0		**High emission scenario** Default from ECHA Guidance R.16 (2016), please refer to Table R.16-7
Fraction released to solid waste	n.a.		
Estimated release to air taking into account all sites	n.a. – 75	kg per year	
Estimated release to wastewater taking into account all sites	n.a. – 75	kg per year	
Estimated release to industrial soil taking into account all sites	n.a. - 0	kg per year	
Estimated amount to solid waste for disposal taking into account all sites	n.a.	kg per year	
Total release taking into account all sites	150	kg per year	

B.9.19.2.1. Workers exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B.9.19.2.2. Consumer exposure

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

B 9.19.2.3. Indirect exposure of humans via the environment

The indirect exposure of humans via the environment is assessed using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The exposure predicted is summarised in the

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Table 57. Estimated indirect local exposure of human via the environment from professional use as laboratory chemical in the EU

Route of exposure of humans via the environment	Lower estimate	Upper estimate	Unit
Daily dose through intake of drinking water	n.a.	2.99E-9	mg/kg bw/d
Fraction of total dose through intake of drinking water	n.a.	0.0002	
Daily dose through intake of fish	n.a.	1E-6	mg/kg bw/d
Fraction of total dose through intake of fish	n.a.	0.0717	
Daily dose through intake of leaf crops	n.a.	4.62E-8	mg/kg bw/d
Fraction of total dose through intake of leaf crops	n.a.	0.0034	
Daily dose through intake of root crops	n.a.	1.23E-5	mg/kg bw/d
Fraction of total dose through intake of root crops	n.a.	0.9128	
Daily dose through intake of meat	n.a.	1.00E-7	mg/kg bw/d
Fraction of total dose through intake of meat	n.a.	0.0074	
Daily dose through intake of milk	n.a.	5.91E-8	mg/kg bw/d
Fraction of total dose through intake of milk	n.a.	0.0044	
Local total daily intake of humans	n.a.	1.35E-5	mg/kg bw/d
Man via environment - inhalation (systemic effects)	n.a.	2.41E-8	mg/m^3
Man via environment – oral	n.a.	1.34E-5	mg/kg bw/d

B.9.19.2.4. Environmental exposure

The environmental exposure assessment has been carried out using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). The PECs estimated for the EU situation are summarised in the **Table 58**.

Table 58. Estimated environmental local exposure from professional use as laboratory chemical in the EU

Compartment	Lower estimate	Upper estimate	Unit
$PEClocal_{freshwater}$	n.a.	1.13E-7	mg/L
$PEClocal_{freshwater\ sediment}$	n.a.	3.58E-3	mg/kg dw
$PEClocal_{marinewater}$	n.a.	1.15E-8	mg/L
$PEClocal_{marinewater\ sediment}$	n.a.	3.64E-4	mg/kg dw
$PEClocal_{STP}$	n.a.	1.56E-6	mg/L
$PEClocal_{air}$	n.a.	2.41E-8	mg/m^3
$PEClocal_{agricultural\ soil}$	n.a.	6.65E-4	mg/kg dw
$PEClocal_{predators'\ prey\ (freshwater)}$	n.a.	3.13E-3	mg/kg ww
$PEClocal_{predators'\ prey\ (marine\ water)}$	n.a.	3.13E-4	mg/kg ww
$PEClocal_{top\ predators'\ prey\ (marine\ water)}$	n.a.	1.04E-3	mg/kg ww
$PEClocal_{predators'\ prey\ (terrestrial)}$	n.a.	1.9E-3	mg/kg ww

B.9.19.3. Qualitative assessment

Introduction

A minor amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. Those two scenarios as well as the corresponding formulation are assessed collectively.

Hence, the overall qualitative assessment of is carried out collectively for the uses as indicated below:

- Formulation, transfer and repackaging of substances in preparations and mixtures,
- Use as solvent/process medium, and
- Use as laboratory chemical by professionals.

General description

A very little amount of Terphenyl, hydrogenated is used as solvent/process medium by the industry or as laboratory chemical by professional. In total the volume used for both uses < 0.5 % of the total volume used in the EU.

Both uses as well as the use "Formulation, transfer and repackaging of substances in preparations and mixtures" are covered in this qualitative assessment.

The only work conducted during the "Formulation, transfer and repackaging of substances in preparations and mixtures" is repacking and transfer of the Terphenyl, hydrogenated.

Since the Terphenyl, hydrogenated is expected to be used as such it is expected that no formulation into mixture or preparation is taking place. However, since no specific information are available to the DS, it cannot be completely excluded that a minor amount will possibly be formulated as well.

For the use as solvent/process medium by the industry and as laboratory chemical by professional very limited information is available to the DS as well.

Environmental exposure

For all three uses assessed here no specific information on the use and the releases to the environment is available. In general, emissions to the environment are possible via releases to the air, water and soil. Further, waste generated during the use of Terphenyl, hydrogenated needs to be taken into account.

Since no specific information is available to the DS the emissions are estimated based on the default release factors as given by the assigned ERCs. Further, for the use as solvent/process medium an ESVOC SpERC (ESVOC SpERC 4.1.z.v2) was available and used as well.

It is indicated in the SpERC factsheet that the use is only conducted indoors but water contact is not excluded. No obligatory RMMs are indicated for the release to air, but oil-water separators are assumed to be in place limiting the release to water. For further information on the SpERC please refer to section B.9.18.1.

Table 59 Estimated releases for the uses assessed in this qualitative assessment

	Formulation	Ind. use as solvent/process medium	Use as laboratory chemical by professionals
Total tonnage used per year (t/y)	36.5	35	1.5
Estimated release to air (kg/y)	912.5	0.4 – 35 000	75
Estimated release to wastewater (kg/y)	730	0.4 – 35 000	75
Estimated release to industrial soil (kg/y)	3.65	3.5 – 1 750	0
Estimated amount to solid waste for disposal (kg/y)	n.a.	1 750	n.a.
Total release (kg/y)	1 646	1 754 – 73 500	150
Percentage of used volume which is released (%)	4.5 %	5 – 210 %	10 %

Especially the total release during the use as laboratory chemical by professional is low (only 150 kg/year). It is however important to set the total release in relation with the total tonnage used per year of the respective use. Estimating the emissions with the default as given by the ERC 4.5 %, 210 % and 10 % is assumed to be released during formulation, industrial use as solvent/process medium and use as laboratory chemical by professionals, respectively.

It has to be emphasized that a release of 210 % is not reasonable since the release cannot be higher than the used tonnage. This overestimation is the result of the very conservative default release factors as given by the ERC. Hence, the refined (low emission scenario) assessment of the industrial use as solvent/process medium is regarded as more realistic leading to only 5 % release.

Moreover, it needs to be pointed out that specific information regarding the amount release to solid waste for disposal is missing for the formulation and the use as laboratory chemical by professionals.

Hence, in this regard the total release is an underestimation of the actual releases. On the other hand, it is reasonable to assume that the amount to solid waste for disposal which is generated during the industrial use as solvent/process medium is treated by certified waste handlers.

Conclusions

Regarding the formulation it is concluded that about 4.5 % of the used volume will possibly be released into the environment, not taking into account solid waste containing Terphenyl, hydrogenated which is produced during the process. Furthermore, information regarding the treatment of the generated waste is not available to the DS.

The releases for industrial use as solvent/process medium derived based on the default release factors of the assigned ERC are not representative since they significantly overestimate the actual emissions. It is concluded that the results of the refined, low emission scenario are more reasonable. Further, it is assumed that the solid waste for disposal which is generated during the industrial use as solvent/process medium is treated by certified waste handlers. Taking the solid waste for disposal out of the equation the total release associated with this use are marginal (4 kg per year). The releases associated with this use would hence be only approx. 0.25 % of the used volume.

For the use as laboratory chemical by professionals no specific information is available to the DS, e.g., it is not known how much will be released via waste. Nevertheless, it appears to be reasonable that the waste generated will be treated by certified waste handlers. The percentage of the used volume which is released (10 %) is high.

Especially the use as laboratory chemical by professionals is of concern. Although only a very small amount (1.5 t/y) of Terphenyl, hydrogenated is used for this application the releases are expected to be high. Further, the treatment of potential solid waste cannot be answered.

Moreover, the evaluation of the formulation scenario is associated with a higher uncertainty, e.g., regarding the amount of waste that is generated and how it is treated.

B.9.20. Use 18: Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves

B.9.20.1. General information

Based on the information obtained through the analysis of the SCIP database the consumer service life as HTF in thermostats in electromechanical temperature controls e.g., in ovens and stoves, was identified.

According to Article 3(3) of REACH the following definition is given for an "article": an article "means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

However, this definition is not appropriate for Terphenyl, hydrogenated which is used as HTF in thermostats (which are used in ovens and similar electronic and electronical equipment). For easier understanding in the following "ovens and similar electronic and electronical equipment" will only be referred to as "ovens".

According to the "Guidance on requirements for substances in articles" (v4, 2017) thermometers which contain a liquid are articles with an integral substance or mixture. Consistent with this described borderline case, oven with thermostats containing Terphenyl, hydrogenated as HTF are also regarded as "article with an integral substance". Hence, the oven is an article as is the thermostat.

Although the oven does not function without a thermostat, the used HTF itself which is used in the thermostat is not an article. It is a liquid which is contained in a closed container that is an essential part of an oven. Consequently, there is no release during the use of the oven and none of the available ERCs is appropriate to describe this case.

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B.9.20.2. Exposure estimation

Based on information included in Chapter B.9.20.1. the estimation of emission is not conducted. As explained the HTF is contained in a closed container that is an essential part of an oven. For this use only the waste life, following at the end-of service life of the articles. The waste life is discussed in Chapter B.9.20.3.

B.9.20.3. Qualitative assessment

Since the consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves is completely independent from the industrial use as HTF and the corresponding laboratory control of the HTF it is not assessed in the qualitative assessment with the other HTF uses. Hence, a separate qualitative assessment is conducted for the consumer use of the stand-alone use "HTF in thermostats".

Based on the information obtained through the analysis of the SCIP database the consumer service life as HTF in thermostats in electromechanical temperature controls e.g., in ovens and stoves was identified.

According to information provided by the lead registrant, the quantity sold on this market is assumed to be <1 t/a, i.e. very small compared to its use as industrial HTF. The lead registrant presumes that the volume of HTF used in ovens is max. 10 ml. This means that a use of 1 t/a is equivalent to 100 000 thermostats or 100 000 ovens.

As explained before, the definition of an "article" (according to Article 3(3) of REACH) is not appropriate for Terphenyl, hydrogenated which is used as HTF in thermostats in ovens. According to the "Guidance on requirements for substances in articles" (v4, 2017) thermometers which contain a liquid are articles with an integral substance or mixture. Consistent with this described borderline case, oven with thermostats containing Terphenyl, hydrogenated as HTF are also regarded as "article with an integral substance". Hence, the oven is an article as is the thermostat.

Although the oven does not function without a thermostat, the used HTF itself which is used in the thermostat is not an article. It is a liquid which is contained in a closed container that is an essential part of an oven.

It is to be noticed that the number of articles containing Terphenyl, hydrogenated imported into the EU and exported from the EU is not known with any certainty. However, with regard to the use of Terphenyl, hydrogenated as HTF in thermostats in electromechanical temperature controls only import into the EU is expected. No information pointing towards assembling the articles within the EU were found/obtained.

Hence, for the use of Terphenyl, hydrogenated as HTF in thermostats in electromechanical temperature controls in e.g., ovens only the service life and the waste life are regarded as relevant.

As indicated before the Terphenyl, hydrogenated is contained in a closed container (the thermostat) inside an article (e.g., an oven) during the service life. Consequently, there is no release during the use of the article, i.e., during the service life of the article containing Terphenyl, hydrogenated as HTF in a thermostat. This leads to the conclusion that there is

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zero release of Terphenyl, hydrogenated associated with the use as HTF in electromechanical temperature controls used in ovens and in similar electronic and electronical equipment.

It is emphasized in Section A.2 that it is in general difficult or even impossible to remove Terphenyl, hydrogenated containing waste from waste streams in an economically feasible way. Nevertheless, as indicated before Terphenyl, hydrogenated is not included into/onto an article in the sense of e.g., ERC 5 when the oven is produced. Rather the Terphenyl, hydrogenated is filled into a vessel (thermostat) which is then assembled with multiple other parts to an oven and similar electronic and electronical equipment. Hence, an oven is an article with an integral substance, the Terphenyl, hydrogenated, which in turn is contained in the closed vessel, the thermostat.

For the end-of service life of ovens and similar electronic and electronical equipment Directive 2012/19/EU on waste electrical and electronical equipment (WEEE) applies. According to Article 1 of Directive 2012/19/EU this Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of WEEE. The WEEE states that Member States (MS) shall ensure that there are systems in place to return WEEE at least free of charge. Further the MS shall ensure the availability and accessibility of the necessary collection facilities (Article 5 of WEEE).

It is also important to notice (Article 6 (2) of WEEE) that MS shall ensure that the collection and transport of separately collected WEEE is carried out in a way which allows optimal conditions for preparing for re-use, recycling, and the confinement of hazardous substances. Thereby MS shall ensure that all separately collected WEEE undergoes proper treatment (Article 8 (1) of WEEE) and proper treatment, other than preparing for re-use, and recovery or recycling operations shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex VII (Article 8 (2) of WEEE).

Under Annex VII of WEEE substances, mixtures and components are indicated which have to be removed from any separately collected WEEE. Amongst others, "hydrocarbons" are indicated. Further it is stated that the indicated mixtures, substances, and components shall be disposed of or recovered in compliance with Directive 2008/98/EC.

Cui and Forssberg (2003) concluded that WEEE consists of a large number of components, some of which contain hazardous components that need to be removed for separate treatment. Further they stated that although the recycling of WEEE is regulated WEEE may cause environmental problems during the waste management phase if it is not properly pre-treated.

It cannot be completely excluded that Terphenyl, hydrogenated will be released (accidentally) by misuse of consumers or during dismantling, recycling, and disposal of WEEE, but no data is available in this regard. Moreover, since the production of electric and electronic equipment (EEE) is one of the fastest growing areas this development will result in an increase of WEEE (Cui and Forssberg (2003)). However, Terphenyl, hydrogenated is only used in ovens, stoves and similar electronic and electronical equipment whereas Cui and Forssberg (2003) indicate a general increase in the production of EEE, not ovens, stoves and similar electronic and electronical equipment in particular. Furthermore, Hischier et al (2005) indicated that the amount of WEEE will increase in Europe at an expected rate of at least 3 to 5 % per year.

However, it is questionable whether there is also an increase in the production of ovens, stoves and similar electronic and electronical which would result in an increase of WEEE and consequently in an increase of Terphenyl, hydrogenated in e-waste.

Furthermore, a reasonable assumption is that the lifetime of ovens, stoves and similar electronic and electronical equipment is up to 20 – 25 years. Moreover, only a few milliliters of Terphenyl, hydrogenated are used in thermostats. Hence, the percentage of the weight of Terphenyl, hydrogenated on the total weight of an oven is very low (significantly lower than 0.1 %).

Conclusion

It is concluded that only a marginal amount of Terphenyl, hydrogenated is used in thermostats used in ovens, stoves, and similar electronic and electronical equipment. During the use of the article by consumers there is no relevant exposure of Terphenyl, hydrogenated since it is contained in a closed vessel which is installed in the article. There are no emissions identified during the consumer use of Terphenyl, hydrogenated as HTF in thermostats in electro-mechanical temperature controls of ovens and stoves.

Furthermore, the disposal of EEE is regulated by the WEEE Directive and Directive 2008/98/EC whereby the handling and separate treatment of fluids and hydrocarbons is explicitly stated. Although it cannot be completely rules out that Terphenyl, hydrogenated could maybe be released during treatment of the e-waste it is assumed that there are usually no emissions of Terphenyl, hydrogenated due to the regulations that are in place. Further, with regard to the lifetime of ovens etc. and the very little amount of Terphenyl, hydrogenated used in thermostats as HTF this use is regarded as of very little concern regarding emissions of Terphenyl, hydrogenated into the environment. No inevitable emissions are expected which need to be minimised.

B.9.21. Other sources (for example natural sources, unintentional releases)

There are no known natural sources of Terphenyl, hydrogenated.

B.9.22. Overall quantitative environmental exposure assessment

B.9.22.1. Summary exposure assessment

The exposure assessment shows that regarding the high emission scenario the "Use as HTF at industrial sites" is by far the most significant emission source. contribute significantly to the overall emission.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 33% of the total emissions followed by Direct use for industrial coatings/inks applications (approximately 25%).

It has to be noted that the imported volume into the EU is the basis for all uses except the two HTF uses. To estimate the exposure associated with the use as HTF at industrial and professional sites the assessment is conducted based the installed volumes instead of the imported volume used as HTF. Thereby, for the industrial use as HTF the highest used tonnage at the largest plant in the EU is used: 1200 tpa. Hence, for the HTF use the assessment is not based on the imported volumes but on the installed volumes since the imported volume would lead to an underestimation. However, it has to be emphasised that at most sites HTF systems with an installed volume of < 50 t are running. Within the EU only 10 sites have an installed volume > 50 t, at 50 sites the installed volume is > 10 t but < 50 t. Additionally, at 40 sites systems a volume < 10 t is installed. In total 100 sites within the EU run a system with Terphenyl, hydrogenated as HTF (For detailed information please refer to **Table 6.** Installed HTF volume and number of sites in 2018 per EU Member State).

The total installed volume, taking into account all of the 100 sites, is determined to be 25 000 tonnes (**Table 4.** Installed base in the EU and uses as HTF).

Hence, taking into account the highest volume installed at a plant (1 200 tonnes) and assuming 100 sites will result in a **vast overestimation since the actual installed volume is exceeded approximately 5 times:**

- Actual installed volume in the EU 25 000 t

- Theoretical installed volume taking into account the installed volume at the largest plant in the EU and the number of sites in the EU: 1 200 tonnes x 100 sites = 120 000 tonnes.

Further, based on the feedback from the stakeholder consultation and individual communication it is determined that in 2020 approx. 6 700 tonnes of Terphenyl, hydrogenated were sold on the EU market, from which around 5 % were used for "top-up" of HTF plants. The top-up or refill demand is driven by the degradation rate of the HTF and the separated low-boiling and high-boiling degradation products. It needs to be understood that the refill cannot be associated with loss of PHT into the environment. In general, this is also contradicting to the estimated releases of the high emission scenario, leaving the fact aside that the release cannot be higher than the amount that is used or in this case "in use".

It is essential, that the above mentioned is taken into account when looking at the result of the quantitative exposure assessment.

Table 60. Emission sources of Terphenyl, hydrogenated

Scenario	**Share of total (%) – Low emission scenario**	**Share of total (%) – High emission scenario**
Manufacture*	0	0
Formulation of coatings/inks	2.67	0.07
Direct use for industrial coatings/inks applications	24.27	1.65
Direct use for professional coatings/inks applications	6.72	0.13
Service life of articles produced from use of coatings and inks	16.95	0.09
Use as HTF at industrial sites	0	94.91
Laboratory analysis	<0.001	<0.001
Formulation of adhesives and sealants	1.49	0.19
Use of adhesives and sealants at industrial sites	6.75	2.17
Use of adhesives and sealants by professionals	5.46	0.23
Service life of articles produced from use as plasticiser	32.02	0.16
Formulation, transfer and repackaging of substances in preparations and mixtures	1.70	0.01
Use as solvent/process medium	1.81	0.39

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Use as laboratory chemical by professionals	0.16	<0.001

*Please notice that there is no manufacture taking place within the EEA.

Regarding the low emission scenario from the use of Terphenyl, hydrogenated as HTF at industrial sites, as stated in **Table 21** of **Annex B.9.3.3.**, 13 sites have contributed to the measured data, although no specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer). Regarding the other 12 sites, they have 17 heat transfer systems installed with a Terphenyl, hydrogenated volume of 2 356 tonnes (2 336 m3). This represents 1% of the sites and 9.8% of the volume of Terphenyl, hydrogenated installed (according to the data included in **Table 6** of **Annex A.2.**).

Among these sites, 8 have systems with a volume of Terphenyl, hydrogenated installed over 50 tonnes, and the other 4 have systems with a volume of Terphenyl, hydrogenated installed between 10 and 50 tonnes. None of the measured sites have systems with a volume of Terphenyl, hydrogenated installed below 10 tonnes.

However, the final calculations for the low emission scenario are estimated through the responses from the SEA questionnaires and the on-site exposure measurements. Both represent a selection of different industries and different company sizes (large and SME). Therefore, the Dossier Submitter believes that the result is representative enough to draw conclusions. In addition, the Dossier Submitter considers that the large range of the different emission scenarios has been taken to have a safety net.

Additionally, the share of total emissions is evaluated based on the market sector (please refer to the following **Table 61**). Thereby the following market sectors are differentiated:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Misc uses (i.e. general formulation, use as solvent and use as lab chemical by professionals)

The analysis showed that the HTF use has by far the largest share of the total emission in the high emission scenario, whereas its share in the low emission scenario is 0 %. It needs to be acknowledged that the share of the HTF use in the high emission scenario is attributed to the use as HTF at industrial sites. However, as indicated before, the volume used in the assessment of the HTF use at industrial sites lead to a vast overestimation and does hence, not represent the actual situation (for further information please refer to Section B.9.3.2.). Consequently, the high share of the total of the high emission scenario and the share of the individual use needs to be interpreted with caution.

In the low emission scenario, the use in coatings/inks has with approx. 50 % the highest share, followed by the use in adhesives/sealants (46 %). The share of the miscellaneous uses is very low for both, the high and low emission scenario.

The releases associated with the individual uses are discussed in the respective qualitative assessment. Please refer to

- ➢ Section B.9.4.3. for the qualitative assessment of the HTF uses,
- ➢ Section B.9.9.4. for the qualitative assessment of the adhesive/sealant uses,
- ➢ Section B.9.13.4. for the qualitative assessment of the coating/ink uses,
- ➢ Section B.9.19.3. for the qualitative assessment of the miscellaneous uses, and
- ➢ Section B.9.20.3. for the qualitative assessment of the consumer use as HTF in thermostats.

Additionally, all findings are summarized in the overall qualitative assessment in Section B.9.23.

Table 61. Emission sources of Terphenyl, hydrogenated based on market sector

Scenario	Share of total (%) Low emission scenario	Share of total (%) High emission scenario
Coatings/inks	50.6	1.94
HTF	0	94.91
Adhesives/sealants	45.73	2.75
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.67	0.40

In the **Table 62** the emissions for each compartment (air, water, and soil) is displayed. These include the sum of estimated releases to the air, water, and soil. However, the redistribution in the STP is not taken into account for emissions to wastewater.

Regarding the low emission scenario approximately the same amount is released to the water and soil compartment (approximately 43 and 39 %, respectively) whereas the release to air is lower (approximately 18 %).

For the high emission scenario approximately 40 % is released to the air as well as the water compartment. Only approximately 21 % is released to the soil.

In general, no major route of emission can be determined.

Table 62. Estimated total EU releases for Terphenyl, hydrogenated

Environmental compartment	Estimated EU emissions based on data on volume for 2021		
	Low (kg per year)	High (kg per year)	Share of total (%)
Air	11 400	710 000	18.18 – 39.82
Water	26 800	706 000	42.74 – 39.6
Soil	24 500	367 000	39.07 – 20.58
All / Total	62 700	1 783 000	100

The estimated regional PECs for Terphenyl, hydrogenated in the EU are summarised in **Table 63**.

Table 63. Estimated regional PECs for Terphenyl, hydrogenated in the EU

Environmental compartment	Lower estimate	Upper estimate	Unit
Fresh water	3.52E-6	6.74E-4	mg/L
Sediment (freshwater)	0.222	42.52	mg/kg dw
Marine water	4.39E-7	7.49E-5	mg/L
Sediment (marine water)	0.028	4.703	mg/kg dw
Air	9.53E-6	3.29E-4	mg/m³
Agricultural soil	6.49E-4	0.022	mg/kg dw

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Man via environment - inhalation (systemic effects)*	9.53E-6	3.29E-4	mg/m^3
Man via environment (oral)**	3.74E-4	0.063	mg/kg bw/d

*expressed as concentration in air
**expressed as exposure via food consumption

In general, the high emission scenario represents a worst-case assumption whereby e.g. the default release factors as indicated in ECHA Guidance R.16 are used. Hence, the high emission scenario has to be regarded as a very conservative approach overestimating the actual exposure. The low emission scenario takes into account information from e.g., SpERC and information obtained in a survey. Hence it is regarded a more realistic emission estimation. Also, the findings are proven by comparable results of the modelling conducted by FABES as well as the monitoring data.

B.9.22.2. Environmental monitoring data

Terphenyl, hydrogenated is a very persistent substance and will have a very long residence time in the environment. It could build up over time and can be widespread in various environmental media. The substance has not been widely found in the environment so far. However, this should not be interpreted as the substance not yet having entered the environment, but that it has previously not been measured in environmental samples. Only a few international measurements of Terphenyl, hydrogenated in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with Terphenyl, hydrogenated resulting potentially from pinhole leaks or faulty joints in the heating coils,, while Sturaro et al. (1995) detected Terphenyl, hydrogenated as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Terphenyl, hydrogenated and diarylethanes, alkyl-naphthalenes, cyclohexane, and dibutyl-phthalate had replaced PCBs as solvent. The use of Terphenyl, hydrogenated in carbonless copy paper has discontinued many years ago.

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including Terphenyl, hydrogenated.

Table 64 summarises the concentrations found in the NILU study.

Table 64. Summary of Terphenyl, hydrogenated concentrations found in environmental samples (NILU, 2018)

Sample Type	Number of Samples	Detection Details	Concentration
Surface Water	9	Dimension Range Average Detection Frequency	ng/l -- -- 0
Wastewater	7	Dimension Range Average Detection Frequency	ng/l 3 – 150 119 100%
		Dimension	ng/g

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Sediment	5	Range Average Detection Frequency	1 – 430 113 100%
Biota	15	Dimension Range Average Detection Frequency	ng/g -- -- 0
Indoor Air	24	Dimension Range Average Detection Frequency	ng/m^3 0.10 – 13 3.8 100%

The substance was found in the 100 ng/g range in marine sediments, which corresponds to a factor of 60 lower, compared to the PNEC in the REACH Dossier. However, it was recommended that the chemical should consequently be studied in more detail.

Terphenyl, hydrogenated was not found in surface waters. Compared to surface water the detection frequency for Terphenyl, hydrogenated were found in all sediment samples, still in low concentrations. Composite river sediment samples were collected a few meters upstream from the river sampling sites at Brubak and Kværnerbyen using a sediment core sampler. Each composite sample consisted of five separate grab samples of the upper two centimeters of the sediments. Marine sediment was collected at two stations, one sample at Hovedøya and two samples at Storøyodden by means of a van Veen grab (0.15 m^2) from RV Trygve Braarud. Three samples of the top layer (0-2 cm with undisturbed surface were prepared in grab samples of four individual grabs each.

Terphenyl, hydrogenated was analysed as well in waste (sewage) water and biota. In all wastewater samples Terphenyl, hydrogenated could be found in concentrations ranging from 3 – 510 ng/l. Regarding samples taken in biota (gull eggs and blue mussel), all concentrations were below the detection limit (< 5 – 15 ng/g ww). The wastewater samples were collected as time-integrated composite samples (50 mL sub-samples every 10 min). Household wastewater samples were collected from a manhole downstream of the residential area during dry weather conditions only with the flowmeter mounted in the 300 mm pipeline entering the same manhole. Industry-influenced wastewater samples were collected from a manhole situated downstream of the industrial areas during both dry weather conditions and at the beginning of heavy rain events.

B.9.23. Overall qualitative environmental exposure assessment

B.9.23.1. Prioritization of uses regarding their contribution to the identified risk

Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves

It is concluded that only a marginal amount of Terphenyl, hydrogenated is used in thermostats used in ovens, stoves, and similar electronic and electronical equipment. During the use of the article by consumers there is no relevant of Terphenyl, hydrogenated since it is contained in a closed vessel which is installed in the article. There are no emissions identified during the consumer use of Terphenyl, hydrogenated as HTF in thermostats in electromechanical temperature controls of ovens and stoves.

Furthermore, the disposal of EEE is regulated by the WEEE Directive and Directive 2008/98/EC whereby the handling of hydrocarbons is explicitly indicated. Although it cannot be completely rules out that Terphenyl, hydrogenated could be released during treatment of the e-waste it is assumed that there are usually no emissions of Terphenyl, hydrogenated due to the regulations that are in place. Further, with regard to the lifetime of ovens etc. and the very little amount of Terphenyl, hydrogenated used in thermostats as HTF this use is regarded as of very little concern regarding emissions of Terphenyl, hydrogenated into the environment. No inevitable emissions are expected which need to be minimised.

Hence, this use is not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated.

Conclusion: This use is not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated.

Heat transfer fluid (Except the "Use as heat transfer fluid in thermostats in electromechanical temperature controls of ovens and stoves")

The releases associated with the laboratory use are regarded as very small (if any). Hence it is concluded that the laboratory use to determine the lifetime of the Terphenyl, hydrogenated used as HTF does not lead to inevitable emissions which need to be minimised.

Taking all information from the Exposure & Release Questionnaire (2018) and the public consultation into account it is safe to say that Terphenyl, hydrogenated is contained in a highly controlled, closed system when used as HTF.

All respondents are well aware that it is crucial to not release any Terphenyl, hydrogenated into the environment.

Consequently, emissions to the environment are regarded as highly unlikely during normal operations. There are no systematic releases when Terphenyl, hydrogenated is used as HTF. Only accidental releases which occur rarely are anticipated. But it was highlighted by multiple respondents in the public consultation that there are systems in place remove and deal with leakage appropriately.

It is hence concluded, that the industrial use of Terphenyl hydrogenated as HTF does not lead to inevitable emissions. Further, it became clear that industry goes to great length to ensure that there is no emission during the running of the HTF system.

The findings are also supported by the exposure measurements which were conducted (for further information please refer to Section B.9.3.3.)

Nevertheless, a Guidance Document on Strictly Controlled Closed Systems (SCCS) is written which will ensure that all HTF system which are run with Terphenyl, hydrogenated fulfil the same standard of "zero emission".

Conclusion: The analysis of the HTF by the supplier are not considered to contribute significantly to the overall risk that is associated with the use of Terphenyl, hydrogenated. The use of Terphenyl, hydrogenated as HTF at industrial sites is already managed appropriately with no emissions to the environment. Regarding both uses the use as HTF at industrial site is not expected to contribute at all to the identified risk, whereas the analysis of the HTF at a lab is regarded as of minor concern regarding the identified risk.

Adhesives/sealants

Regarding the formulation it is concluded that < 1 – 7.51 % of the used volume will possibly be released into the environment. However, it us assumed that it can be expected that that solvent waste is handled appropriately by certified waste handlers which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional cannot be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all waste would be handled and recycled accordingly emissions into the environment are expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable, whereas the professional end-use is more critical than the industrial end-use.

Regarding the service life of article no specific information are available to the DS. A constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

Conclusion: The formulation as well as the industrial use of adhesives and sealants are regarded as of minor concern and are not expected to contribute significantly to the identified risk. However, the professional use is identified as critical, especially when the sealants/adhesives containing Terphenyl, hydrogenated are used outdoors. Furthermore, the service life of articles containing Terphenyl, hydrogenated is regarded as critical and actual emissions are uncertain due to the lack of specific information. Concluding that the service life as well as the professional use will contribute significantly to the identified risk.

Coatings/inks

Regarding the formulation it is concluded that about 1 – 5.5 % of the used volume will possibly be released into the environment. However, it us assumed that it can be expected that process waste may be recycled or incinerated by waste disposal company which would result in an even lower release.

Regarding the end-uses a release, especially when used by professional can not be denied. Especially when used outdoors a release to water and soil is highly likely. Even if all the process waste would be recycled or incinerated the assumed emissions into the environment can still be expected. Due to the lack of information, it is uncertain whether further RMMs are in place which reduce emissions. Hence, it is concluded that for the two end-uses emission are inevitable.

Regarding the service life of article no specific information are available to the DS. However, a constant release is expected although the amount that will possibly be release is unclear. Further, the treatment of disposed articles coated with a coating containing Terphenyl, hydrogenated is uncertain. Hence, it is concluded that the service life scenario is associated with a high uncertainty, but emissions are regarded as inevitable.

Conclusion: The formulation of coatings and inks is regarded as of minor and the industrial use of coatings and inks is regarded as of moderate concern regarding the identified risk. However, the professional use is identified as critical, especially when the coatings/inks containing Terphenyl, hydrogenated are used outdoors. Furthermore, the service life of articles containing Terphenyl, hydrogenated is regarded as critical and actual emissions are uncertain due to the lack of specific information. Concluding that the service life as well as the professional use will contribute significantly to the identified risk.

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Miscellaneous uses

Regarding the formulation it is concluded that about 4.5 % of the used volume will possibly be released into the environment, not taking into account solid waste containing Terphenyl, hydrogenated which is produced during the process. Furthermore, information regarding the treatment of the generated waste is not available to the DS.

The releases for industrial use as solvent/process medium derived based on the default release factors of the assigned ERC are not representative since they significantly overestimate the actual emissions. It is concluded that the results of the refined, low emission scenario are more reasonable. Further, it is assumed that the solid waste for disposal which is generated during the industrial use as solvent/process medium is treated by certified waste handlers. Taking the solid waste for disposal out of the equation the total release associated with this use are marginal (4 kg per year). The releases associated with this use would hence be only approx. 0.25 % of the used volume.

For the use as laboratory chemical by professionals no specific information is available to the DS, e.g., it is not known how much will be released via waste. Nevertheless, it appears to be reasonable that the waste generated will be treated by certified waste handlers. The percentage of the used volume which is released (10 %) is high.

Especially the use as laboratory chemical by professionals is of concern. Although only a very small amount (1.5 t/y) of Terphenyl, hydrogenated is used for this application the releases are expected to be high. Further, the treatment of potential solid waste cannot be answered.

Moreover, the evaluation of the formulation scenario is associated with a higher uncertainty, e.g., regarding the amount of waste that is generated and how it is treated.

Conclusion: Of the three herein assessed uses the formulation and the use as laboratory chemical by professional are regarded as potentially problematic. Due to the lack of information the question of how waste is treated cannot be answered sufficiently. Hence, the two indicated uses are regarded as of moderate concern regarding the identified risk.

B.9.23.2. Summary of prioritization & conclusion

Table 65 Prioritization of uses based on their contribution to the identified risk.

Identified Use	**Market Sector**
Uses assumed to contribute significantly to the identified risk	
Articles produced from use as plasticiser	Adhesives/sealants
Use of adhesives and sealants by professionals	Adhesives/sealants
Articles produced from use of coatings and inks	Coatings/inks
Direct use for professional coatings/inks applications	Coatings/inks
Uses assumed to be of moderate concern regarding the identified risk	
Direct use for industrial coatings and inks applications	Coatings/inks

Uses assumed to be of minor concern regarding the identified risk	
Formulation of adhesives and sealants	Adhesives/sealants
Use of adhesives and sealants at industrial sites	Adhesives/sealants
Formulation of coatings or inks	Coatings/inks
Use in laboratory analysis	HTF
Formulation, transfer, and packing of substances in preparations and mixtures	Misc.
Use as solvent or process medium	Misc.
Use as laboratory chemical by professionals	Misc.
Uses assumed to be of negligible concern regarding the identified risk	
Use as HTF at industrial sites	HTF
Consumer service life as HTF in thermostats in electromechanical temperature controls of ovens and stoves	Stand-alone HTF use

B.9.23. Human exposure assessment

B.9.2.4.1. General

Generally, exposure can occur through 1) workers exposure, 2) consumer exposure and 3) indirect exposure of humans via the environment. However, the exposure through workers and consumer exposure is not considered in this dossier, as the restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated, hence, the assessment of human health effects is not conducted. Only the assessment of the exposure to Terphenyl, hydrogenated through indirect exposure of humans via the environment is carried out.

In principle, exposure can either be estimated by 1) calculating the external dose by multiplying measured or modelled concentrations of Terphenyl, hydrogenated from different sources (e.g. food, air and drinking water) with exposure factors (e.g. inhalation rate or volume/amount consumed), or 2) assessing the internal dose by measuring concentrations of the substance in biological matrix (e.g. blood, hair, fat tissue or breast milk), which further can be used to calculate the body burden based on the knowledge of toxicokinetic behaviour. Information on internal concentrations is normally obtained via human biomonitoring data, however no such data exist for Terphenyl, hydrogenated. The fact that human biomonitoring data for Terphenyl, hydrogenated are not available was also stated in a recent report of the Health Council of the Netherlands providing Health-based recommendation on occupational exposure limits on hydrogenated terphenyl (HCN, 2020).

Information on accumulation in biological matrices is limited to measurements in biota. As given under B.9.21.2. Environmental monitoring data, Terphenyl, hydrogenated samples were taken in biota gull eggs and blue mussel. The measurements revealed that all concentrations were below the detection limit (< 5 – 15 ng/g w/w). Due to the limited data, this result can provide an indication that no accumulation of Terphenyl, hydrogenated is to be expected in biological matrices.

Due to the lack of human biomonitoring data, in this section exposure to Terphenyl, hydrogenated has primarily been described by available measurements of Terphenyl, hydrogenated in indoor and outdoor environments, as given in more detail in the following chapter. The assessment of indirect exposure of humans via the environment is then conducted using EUSES v2.1.2 (ECHA, 2022b) as implemented in CHESAR v3.7 (ECHA, 2022a). Please refer to the corresponding chapters under B.9.1-B.9.21.

B.9.24.2. Detected/measured levels regarding consumers exposure

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including Terphenyl, hydrogenated.

Table 66 summarises the concentrations found in the NILU study (NILU, 2018).

Table 66. Summary of Terphenyl, hydrogenated concentrations found in environmental samples (NILU, 2018)

Sample Type	Number of Samples	Detection Details	Concentration
Indoor Air	24	Dimension Range Average Detection Frequency	ng/m^3 0.10 – 13 3.8 100%

In addition, Terphenyl, hydrogenated was measured in buildings in house dust. Screening of indoor environments was performed by collecting settled floor dust samples and passive air samples from 16 residential buildings and five non-residential buildings in the Oslo area. The sampling locations also includes sites that represent different levels of population density, from the urban center of Oslo to the semi-rural areas around Oslo. The non-residential buildings included offices, a school, and one veterinary clinic. Passive air samples were collected using two types of samplers: i) polyurethane foam passive air samplers (PUF-PAS), and ii) XAD resin PAS (XAD-PAS). Analytical data shows in general a much lower concentration in non-residential buildings. However, there is one single case of extreme air concentration (13 ng/m^3).

According to the dossier submitters interpretation, these concentration levels are likely resulting from the use of Terphenyl, hydrogenated in plasticiser applications, e.g., from plastics in building materials or plasticiser applications in electronics. We do not share the interpretation of the study authors that the concentrations in indoor air are resulting from the use as HTF. It is assumed that other uptake routes are more relevant than inhalation.

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Figure 26. Comparison of air concentrations of the sum of all measured Terphenyl, hydrogenated in residential and non-residential indoor environments (NILU, 2018)

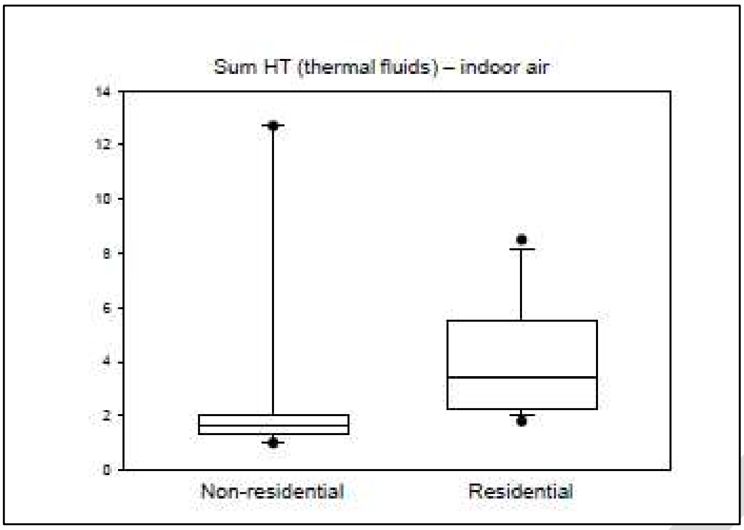

Figure 27 provides a full copy of the analytical results table from the NILU study (NILU, 2018).

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Figure 27. Analytical results table from the NILU study (NILU, 2018)*

* Please note that commas separate decimal values

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Matrix/ Sampling site		H18pT	sH12mT	uH12mT	uH12pT	sH12pT	uH6mT	csH6mT	tsH6pT	Sum HT
Sewage water										
Alna 1, Hellerud,Pr.1	ng/L	<300	<33	<35	<30	<30	<20	**12**	<9,1	**16**
Alna 1, Hellerud,Pr.2	ng/L	<28	<5,2	<5,5	<4,5	**20**	**6,3**	**9,4**	**2,4**	**40**
Alna 1, Hellerud,Pr.3	ng/L	<580	<131	<140	<113	**490**	<21	**15**	<10	**510**
Alna 2.Ind.omr. Pr 1	ng/L	**148**	<6,2	<3,8	<3,1	**20**	<4,2	**10**	**6,8**	**182**
Alna 2.Ind.omr. Pr 2	ng/L	<120	<140	<14	<12	**33**	<7,8	**14**	**4,8**	**55**
Alna 2.Ind.omr. Pr 3	ng/L	<30	<33	<34	<28	<29	<40	<20	<18	**3,0**
Alna 2.Ind.omr. Pr 4	ng/L	<60	<8,5	<8,8	<7,4	**12**	<9,8	**6,6**	<4,7	**26**
Surface water										
Alna 3,Veslt.tj. Pr. 1	ng/L	<17	<3,3	<2,9	<2,7	<2,7	<2,7	<2,1	<1,9	<25
Alna 4,Brubak, Pr. 1	ng/L	<30	<5,8	<5,1	<4,7	<4,8	<4,8	<3,7	<3,4	<7
Alna 4,Brubak, Pr. 2	ng/L	<7,5	<1,4	<1,3	<1,2	<1,2	<1,2	<0,9	<0,8	<10
Alna 4,Stikkpr, Pr. 4	ng/L	<3,3	<3,1	<2,8	<2,5	<2,6	<2,6	<2	<1,8	<7
Alna 5,Kværner,Pr. 1	ng/L	<5	<1	<0,9	<0,8	<0,8	<0,8	<0,6	<0,6	<7
Alna 5,Kværner,Pr. 2	ng/L	<8,7	<1,7	<1,5	<1,3	<1,4	<1,4	<1,1	<1	<10
Alna 5,Kværner,Pr. 3	ng/L	<18,8	<1,8	<1,6	<1,5	<1,5	<1,5	<1,1	<1,1	<20
Alna 5,Kværner,Pr. 4	ng/L	<8,8	<1,7	<1,5	<1,4	<1,4	<1,4	<1,1	<1	<10
Alna 5,Stikkpr.,Pr. 5	ng/L	<7,9	<1,5	<1,3	<1,2	<1,3	<1,3	<1	<0,9	<10
Sediment										
Hovedøya	ng/g dw	**112**	<1,22	<1,32	<1,11	**8,7**	**3,1**	**1,7**	<1,32	**130**
Storøyodden 1/2	ng/g dw	<0,41	<0,16	<0,18	<0,15	**1,1**	<0,21	**0,11**	<0,09	**1,1**
Storøyodden 2/2	ng/g dw	<0,79	<0,15	<0,17	<0,14	**0,99**	<0,2	<0,15	<0,13	**0,99**
Alna 4. Brubak	ng/g dw	<0,86	<0,17	<0,18	<0,15	**1,8**	<1,12	**0,21**	<0,46	**1,8**
Alna 5, Kværner	ng/g dw	**2,5**	**92**	**31**	**3,6**	**85**	**26**	**105**	**65**	**430**
Blue mussel										
Hovedøya 1	ng/g ww	<3,83	<1,88	<2,04	<1,71	<1,56	<2,48	<1,17	<1,02	<5
Hovedøya 2	ng/g ww	<5,43	<2,66	<2,89	<2,43	<2,22	<3,52	<1,66	<1,44	<5
Storøyodden 1	ng/g ww	<6,33	<0,41	<0,45	<0,38	<0,34	<1,37	<0,65	<0,56	<10
Storøyodden 2	ng/g ww	<7,69	<0,75	<0,82	<0,69	<0,63	<1	<0,47	<0,41	<10
Storøyodden 3	ng/g ww	<4,72	<0,46	<0,5	<0,42	<0,38	<1,02	<0,48	<0,42	<5
Gull egg										
Søndre Skjælholmen	ng/g ww	<6,06	<0,66	<0,67	<0,56	<0,59	<0,79	<0,44	<0,38	<15
Søndre Skjælholmen	ng/g ww	<5,6	<0,61	<0,62	<0,51	<0,54	<0,73	<0,4	<0,35	<15
Søndre Skjælholmen	ng/g ww	<4,69	<0,51	<0,52	<0,43	<0,46	<0,61	<0,34	<0,3	<15
Søndre Skjælholmen	ng/g ww	<5,5	<0,6	<0,61	<0,51	<0,53	<0,72	<0,4	<0,35	<15
Søndre Skjælholmen	ng/g ww	<5,62	<0,61	<0,62	<0,52	<0,55	<0,74	<0,41	<0,35	<15
Søndre Skjælholmen	ng/g ww	<5,86	<0,64	<0,65	<0,54	<0,57	<0,77	<0,42	<0,37	<15
Søndre Skjælholmen	ng/g ww	<6,27	<0,69	<0,69	<0,58	<0,61	<0,82	<0,45	<0,4	<15
Søndre Skjælholmen	ng/g ww	<6,54	<0,71	<0,72	<0,6	<0,63	<0,86	<0,47	<0,41	<15
Søndre Skjælholmen	ng/g ww	<5,17	<0,56	<0,57	<0,47	<0,5	<0,68	<0,37	<0,33	<15
Søndre Skjælholmen	ng/g ww	<6,08	<0,66	<0,67	<0,56	<0,59	<0,79	<0,44	<0,38	<15

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Matrix/ Sampling site		H18pT	sH12mT	uH12mT	uH12pT	sH12pT	uH6mT	csH6mT	tsH6pT	Sum HT
House dust										
House 1 a	ng/m3	<1,74	**1,1**	<0,39	<0,36	**5,3**	<0,27	**0,51**	**0,24**	**7,6**
House 2	ng/m3	<1,24	**1,2**	**0,46**	<0,17	**1,8**	**0,37**	**0,79**	**0,35**	**5,7**
House 3	ng/m3	<1,06	**0,35**	<0,24	<0,22	**1,4**	<0,17	**0,15**	<0,10	**2,1**
House 4	ng/m3	<0,71	**0,57**	<0,21	<0,19	**1,1**	**0,10**	**0,18**	**0,09**	**2,2**
House 5	ng/m3	<2,02	**1,7**	**0,76**	<0,28	**2,4**	**0,51**	**1,2**	**0,54**	**8,0**
House 6	ng/m3	<1,30	**0,91**	**0,36**	<0,18	**2,1**	**0,25**	**0,41**	**0,18**	**4,5**
House 7	ng/m3	<0,59	**1,4**	**0,42**	**0,09**	**0,98**	**0,22**	**0,87**	**0,37**	**4,9**
House 8 a	ng/m3	<2,70	**0,95**	<0,41	<0,37	**0,20**	<0,21	**0,34**	**2,4**	**4,2**
House 9	ng/m3	<0,68	**0,45**	<0,21	<0,19	**2,0**	**0,11**	**0,14**	**0,07**	**2,9**
House 10	ng/m3	<1,31	**0,54**	<0,28	<0,25	**1,3**	<0,20	**0,26**	<0,12	**2,3**
House 11	ng/m3	<1,64	**0,50**	<0,25	<0,23	**1,2**	<0,13	**0,20**	**0,08**	**2,2**
House 12	ng/m3	<3,30	**0,59**	<0,31	<0,28	**1,2**	**0,26**	**0,30**	**0,12**	**2,7**
House 13	ng/m3	<3,29	**0,68**	<0,50	<0,45	**1,2**	**0,16**	**0,34**	**0,18**	**2,8**
House 14	ng/m3	<4,54	**0,74**	<0,34	<0,31	**2,6**	<0,21	**0,36**	<0,13	**4,0**
House 15	ng/m3	<1,58	**1,9**	**0,61**	<0,17	**3,5**	<0,49	**1,0**	**0,54**	**8,5**
House 16	ng/m3	<0,98	**0,29**	<0,11	<0,10	**1,1**	<0,11	**0,13**	<0,07	**1,8**
House 17	ng/m3	<0,98	**0,34**	<0,19	<0,14	**0,86**	<0,12	**0,19**	**0,07**	**1,7**
House 18	ng/m3	<0,37	**0,25**	<0,11	<0,10	**0,84**	<0,09	**0,14**	<0,05	**1,3**
House 19	ng/m3	<0,20	**0,13**	<0,09	<0,08	**0,64**	<0,04	**0,07**	<0,03	**1,0**
House 20	ng/m3	<1,03	**0,19**	<0,12	<0,11	**0,98**	**0,08**	**0,10**	<0,05	**1,7**
House 21	ng/m3	<0,44	**0,28**	**0,11**	<0,03	**0,37**	**0,06**	**0,13**	**0,06**	**1,3**
House 22	ng/m3	<1,24	**0,56**	**0,44**	<0,17	**11**	**0,21**	**0,26**	**0,13**	**13**
House 23	ng/m3	<0,91	**0,32**	**0,11**	<0,04	**0,79**	**0,11**	<0,47	**0,09**	**1,5**
House 24	ng/m3	<0,50	**0,41**	**0,16**	<0,05	**0,86**	**0,01**	**0,24**	**0,10**	**2,1**

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Terphenyl, hydrogenated as a substance is not included in the European Pollutant Release and Transfer Register (E-PRTR), which is based on Regulation (EC) No 166/2006[36] and COM Implementing Decision 2019/1741.[37] E-PRTR is a Europe-wide register of environmental release data from industrial facilities in European Economic Area (EEA) Member States[38] established under Regulation (EC) No 166/2006. It contains data reported annually from 2007 onwards by some 30.000 industrial facilities covering 65 economic activities across Europe, including information concerning the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and pollutants in wastewater. Release and transfer data are reported on 91 key pollutants (Annex II to Regulation (EC) No 166/2006) including heavy metals, pesticides, greenhouse gases, and organic chemicals. Industrial facilities that undertake one or more of the activities specified in Annex I to Regulation (EC) No 166/2006 must annually report release and transfer data (unless they stay below the capacity thresholds).

Synthetic HTFs, like Terphenyl, hydrogenated, can be captured by a specific waste code. A standard coding system classifies and describes the type of waste. These are called EWC Codes (European Waste Codes) as specified in the EU Waste Legislation[39].

Figure 28. Waste codes of synthetic HTFs. Waste marked with an asterisk (*) in the list of wastes shall be considered as hazardous waste

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13 03 07*	mineral-based non-chlorinated insulating and heat transmission oils
13 03 08*	synthetic insulating and heat transmission oils
13 03 09*	readily biodegradable insulating and heat transmission oils
13 03 10*	other insulating and heat transmission oils

B.9.24.3. Indirect exposure of humans via the environment

This restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier

B.9.24.4. Combined human exposure assessment

Generally, the combined human exposure assessment considers exposure from all sources. However, this restriction dossier is based on the established vPvB properties of Terphenyl, hydrogenated. Hence, the assessment of human health effects is therefore not conducted in this dossier.

[36] European Industrial Emissions Portal (europa.eu)
[37] EUR-Lex - 32019D1741 - EN - EUR-Lex (europa.eu)
[38] The EEA includes EU countries and also Iceland, Liechtenstein and Norway.
[39] EU Waste Framework Directive 2008/98.

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B.10. Risk characterisation

It is not relevant to perform quantitative risk assessments of vPvB substances, due to the uncertainties regarding long-term exposure and effects. Therefore, the risks of vPvB substances, such as Terphenyl, hydrogenated, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for vPvB substances is to minimise the exposures and emissions to humans and the environment (REACH Regulation, Annex I, section 6.5):

"For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, RMMs which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or IU".

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Annex C: Justification for action on a Union-wide basis

Terphenyl, hydrogenated has been identified as an SVHC based on its vPvB properties according to Article 57(e) of the REACH Regulation. In addition, on 14 April 2021 ECHA has recommended the substance for the inclusion in Annex XIV to REACH (List of Substances subject to Authorisation). This 10th ECHA Recommendation[40] is based on the inherent properties (vPvB), the volume and the wide dispersiveness of uses (industrial sites, professional workers and use in articles).

As outlined before, Terphenyl, hydrogenated is chemically very stable in various environmental compartments with minimal or no abiotic degradation and is very bioaccumulative, which means that environmental stock may increase over time upon continued releases. For vPvB substances a safe concentration level in the environment cannot be established with sufficient reliability and for this reason, vPvB substances are treated as non-threshold substances for the purpose of risk management under REACH. For these substances, for which it is not possible to establish a safe level of exposure, RMMs should always be taken to minimise exposure and emissions, as far as technically and practically possible (recital 70 of the REACH Regulation). Due to this fact, even small levels of environmental emissions of this kind of substances could be considered sufficient to demonstrate their risk.

When Terphenyl, hydrogenated is used as an HTF, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated under "**Annex B.9**.: Exposure Assessment". During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.). Potential emissions to the environment are prevented by the implementation of stringent containment measures and control during the design stage of the closed system. Other exposure and emission sources of Terphenyl, hydrogenated when used as HTF are related to transport, loading and refilling operations, replacement or topping-up of the HTF, industrial cleaning operations, and disposal of the HTF.

When Terphenyl, hydrogenated is used as a plasticiser it is released into the environment during the various life cycle steps. The LR has conducted a comparative risk assessment for the two main uses, HTF and plasticiser (Solutia, 2018). The calculation clearly showed that the plasticiser use is far more critical for risk management than the HTF use.

The estimated local and regional overall release associated with the use as a plasticiser is up to 10-times higher than the local and regional overall release associated with the use as an HTF, respectively. It was shown that the total environmental emissions based on the use of Terphenyl, hydrogenated as an HTF are significantly lower than the total releases from the plasticiser uses. The use of the substance as a plasticiser is more critical for risk management regarding the emissions to the environment than the use as an HTF within a closed system.

These results have been confirmed by the Environmental Monitoring program at HTF sites and migration modelling studies on plasticiser uses, conducted by the LR (see **Annex B.9.**: Exposure Assessment).

Moreover, for the plasticiser use Terphenyl, hydrogenated will be incorporated into/onto an article. At the end of the service life of the article, it has to be disposed. During the disposal at a WWTP the Terphenyl, hydrogenated may be released into the environment as well. Consequently, the end of the article's service life leads to the generation of waste containing the substance and the final disposal may lead to additional releases to the environment. As shown in **Annex A** (Manufacture and Uses), in total more than 12 000 articles containing Terphenyl, hydrogenated have been notified to the SCIP database. Most entries are related to the use in polymers, rubber, and elastomers (> 60%), sealants (> 25%), inks (> 5%), sensors (< 1%), paper (> 1%) and a few others. In summary it can be concluded that close

[40] Submitted recommendations - ECHA (europa.eu)

to 85% of Terphenyl, hydrogenated use in articles is related to plasticiser uses. Therefore, there is also significant potential for release of Terphenyl, hydrogenated to the environment from waste disposal activities (see Annex B.9.: Exposure assessment”). The dossier submitter assumes, that at the waste life-cycle stage of articles, the operational conditions and risk management measures are not sufficient and effective enough to control the risks of Terphenyl, hydrogenated.

The Dossier Submitter assumes that articles notified to the SCIP database are small and parts of very complex products, like vehicles (cars, trains, planes), Electrical and Electronic Equipment (EEE), construction and building components, or furnishings. Complex products are products, which are composed of multiple components which can be replaced permitting disassembly and re-assembly of the product.

These products will be used widespread. Separation and properly management of Terphenyl, hydrogenated containing parts in the waste phase seems unrealistic. Therefore, Terphenyl, hydrogenated containing waste from articles cannot be removed from waste streams in an economically feasible way. In addition, high recycling rates required for different waste streams (e.g., end-of-life vehicles, waste EEE recycling) in the EU and as well the Circular Economy prohibit large-scale incineration. In addition, the capacity of high-temperature incineration could be an issue due to the large volumes of wastes from EEE and the automotive sector.

Please note, for some chemicals, most human and environmental exposures occur through product use and disposal, rather than in the manufacturing stage. For example, in the case of DEHP, used as a plasticizer in polymer products, about 95% of the emissions occur from end-product uses and waste handling.

Referring to the Dechlorane Plus (DP) Restriction Report (ECHA, 2021d), DP was released to the environment significantly during use phase and from waste disposal and recycling activities. On a global scale, the highest DP concentrations were detected close to known production sites or electronic waste (e-waste) treatment facilities. The use of DP in articles was as well recommended to be banned.

The DS submitter therefore assumes, that current OC’s and RMMs are not sufficient to address the concern at the waste-stage and therefore a complete restriction of Terphenyl, hydrogenated use in articles (> 0.1% w/w) is the most appropriate risk management measure. An estimation of costs related to these measures is therefore not possible

Terphenyl, hydrogenated has not been widely found in the environment so far. However, this should not be interpreted as the substance not yet having entered the environment, but that it has previously not been measured in environmental samples. Only a few international measurements of Terphenyl, hydrogenated in the environment or other media have been reported. Moh et al. (2002) describe accidental contamination of food items with Terphenyl, hydrogenated, while Sturaro et al. (1995) detected Terphenyl, hydrogenated as contaminant in food cardboard packages made from recycled material containing carbonless copy paper.

A screening programme conducted in 2018 by the NILU and the NIVA (NILU, 2018), has focused on the occurrence and expected environmental problems of several chemicals, which were selected based on possible PBT properties, including Terphenyl, hydrogenated. The substance was found in the 100 ng/g range in marine sediments, and it was recommended that the chemical should consequently be studied in more detail. Compared to surface water the detection frequency for hydrogenated terphenyls were found in all samples, still in low concentrations. In addition, Terphenyl, hydrogenated was measured in buildings. Analytical data shows in general a much lower concentration in non-residential buildings. However, there is one single case of extreme air concentration which might be due to leakage from technical installations in this building.

Since Terphenyl, hydrogenated persists in the environment for a very long time and it has the potential to accumulate in humans and wildlife, effects of current emissions may be observed or only become apparent in future generations. Avoiding effects will then be difficult due to the irreversibility of exposure. The main benefits to society from a partial restriction of Terphenyl, hydrogenated will be the avoidance of these potential transgenerational impacts on the environment and human health in the future, through proportionate reductions in emissions and exposure to this substance.

It is therefore desirable to go ahead with a Restriction under REACH in order to benefit from an early implementation of emission reduction. Consequently, an EU Restriction will be an important step to reduce the emissions and risks from Terphenyl, hydrogenated within the EU internal market.

National regulatory actions are not considered adequate to manage the risks – in particular the risk on the plasticizer uses. Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to actions undertaken by individual Member States.

A description of the proposed Union-wide Restriction Option (RO) that has the potential to reduce emissions of Terphenyl, hydrogenated to the environment is presented in **Annex E.1.** (Risk Management Options). A corresponding EU-wide restriction will prevent and reduce the releases of the substance and is considered to be the most efficient and appropriate way to limit the risks (due to further releases into the environment) for human health and the environment on an EU level.

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Annex D: Baseline

D.1. Introduction

The baseline scenario is the situation in the absence of the proposed restriction or any further RMM, or interventions implemented to reduce the environmental risks from manufacture, import and use of Terphenyl, hydrogenated. The baseline is a projection of future Terphenyl, hydrogenated volumes used in the EU and the corresponding projected releases of Terphenyl, hydrogenated into the environment. The projections consider other external factors that could affect the market, such as implementation of new legislations/regulations or changes to existing ones that may affect the releases of Terphenyl, hydrogenated. The baseline scenario describes the "business as usual" situation.

The baseline was developed based on the data gathered on manufacture, import and use of Terphenyl, hydrogenated within the EU as presented in **Annex A** (Manufacture and Uses) and the Exposure Assessment as outlined in **Annex B.9**.

The period from which the baseline is derived was chosen to be 2025 – 2044 as 2025 is considered the earliest, realistic Entry into Force (EiF) for a potential REACH restriction on Terphenyl, hydrogenated and 20 years is the analytical period commonly used for most restriction proposals.

The tonnage and releases report in **Annex A** (Manufacture and Uses) and **Annex B.9.** (Exposure Assessment) are the starting point for the baseline in this analysis and the assumptions related to future trends of the use of Terphenyl, hydrogenated. The baseline scenario is compared to the proposed restriction scenario in the Impact Assessment (**Annex E**) in terms of both costs and benefits.

D.2. Existing Regulations affecting the Manufacture and Use of Terphenyl, hydrogenated

There is currently no regulation at EU level which is significantly affecting the manufacture and use of Terphenyl, hydrogenated. There are some indications that SVHC identification could affect the baseline, mainly for their use in non-HTF applications.

According to personal communication with representatives from the adhesives & sealants industry (use as a plasticiser), SVHC listing makes additives less attractive for mid- to long-term formulation developments, due to the perceived threat they could become subject to REACH Authorisation at any time. The decreasing participation in the SEA questionnaires from 2018 to 2020 and 2021 (see **Annex E**: Impact Assessment) suggests as well that the industry involved in the plasticiser use has started the reformulation/ substitution process already.

Moreover, it should be noted that Annex I of REACH obliges registrants of PBT/vPvB substances to implement or recommend to downstream user RMMs that minimise the releases of substances to environmental compartments and the workplace throughout the life cycle of the substance. Use of a PBT/vPvB substances in a consumer product that has a "widely dispersed" use (either released to the atmosphere or to wastewater), is unlikely to be consistent with the concept of minimisation. Therefore, it could be argued that the identification of Terphenyl, hydrogenated as SVHC is sufficient justification itself for producers to reformulate sealants & adhesives products.

The current version of the CLP Regulation, which implements the GHS, does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, CLP Regulation is currently being updated and PBT/vPvB are likely to be included as hazard classes in the future.

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The EU Water Framework Directive (Directive 2000/60/EC)[41] provides a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as "Priority Substances" and further requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges and losses of the Priority Substances (PS) and to phase out those deemed the most harmful ones ("Priority Hazardous Substances", PHS). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC)[42] for PS and PHS[43]. Member States must ensure that the EQS for the Priority Substances are met in order to achieve "good chemical status" in accordance with Water Framework Directive Article 4 and Annex V 1.4.3[44]. The Priority Substances list was replaced in 2013 via Directive 2013/39/EU[45], which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. Terphenyl, hydrogenated is currently not identified as a PS or PHS.

The Industrial Emissions Directive (2010/75/EU)[46] establishes the main principles for permitting and control large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection.

The manufacture and some uses of Terphenyl, hydrogenated are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents[47] related to the use of Terphenyl, hydrogenated are available, the IED is considered of limited applicability for the risk management of the substance.

From an EU policy standpoint, the COM's new Circular Economy Action Plan announces initiatives along the entire life cycle of products. It targets their design and promotes circular economy processes to stimulate sustainable consumption. It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC) sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, as well as to improve the efficient use of resources. An amendment[48] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit to ECHA information via the SCIP Database, thus providing waste operators information about hazardous substances in the waste processed.

D.3. Current Situation on Volumes and Baseline Volumes

To be able to estimate the expected impact of the restriction proposal, it is important to know the current situation in terms of the use of Terphenyl, hydrogenated in the EU and to describe the expected trends that would occur without the introduction of any new regulatory measure.

[41] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy.
[42] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.
[43] http://ec.europa.eu/environment/water/water-dangersub/index.htm
[44] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000L0060-20141120
[45] Directive 2013/39/EU of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.
[46] Directive 2010/75/EU of the European Parliament and the Council on industrial emissions.
[47] BAT reference documents | Eippcb (europa.eu)
[48] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste.

From 2025 to 2044, it is expected that developments in the volume of Terphenyl, hydrogenated used as HTF in the EU will be dominated by the market trends. As shown before, Terphenyl, hydrogenated plays a significant role as HTF in alternative energy technology (ORC and solar) supporting the EU's Green Deal[49]. Moreover, chemical recycling of PET and other polymers is increasing following the EU's Circular Economy action plan[50]. The dossier submitter therefore assumes, that the growth trend as shown will continue in the next 20 years, but slightly levelled due to the SVHC listing. In addition and due to the feedback from the different questionnaires, the demand for Terphenyl, hydrogenated was higher than the available production capacity in the last 5 years, therefore new production plants have been installed in China and the Middle East.

This resulted in growth rates of up to 30% in the last 3 years globally as well as on EU level. It is reasonable to assume that this growth rate will flatten as more capacity has been installed globally and a continued volume increase of 5% annually for HTF use is assumed by the Dossier Submitter, resulting in a predicted volume for HTF use of ca. 16 931 tonnes per year by end of 2044.

The Dossier Submitter understands that the Gross Domestic Product (GDP) in the EU is considered to be significant below 5% on average and for the years 2022 and 2023 the GDP in the EU should be in the area of 2.3 – 2.7%. The current pandemic situation and the war in Ukraine are leaving further question marks about the future development. However, it is important to note, that Terphenyl, hydrogenated is used in certain key renewable energy technologies such as CSP and ORC. Concentrated Solar Power (CSP) is an innovative technology to transfer heat from the solar collectors to the power cycle. Organic Rankine Cycle (ORC) are considered to be a next generation technology as well for power generation from residual heat, for example for cost-effective power generation using waste or biomass heat from combustion or production processes.

Due to the Circular Economy, the EU Green Deal and the current energy crisis in Europe, these technologies are growing strongly and justifying a growth rate value above GDP.

Figure 29 below shows the estimated volume development in the EU between 2025 and 2044, based on the aforementioned growth rates.

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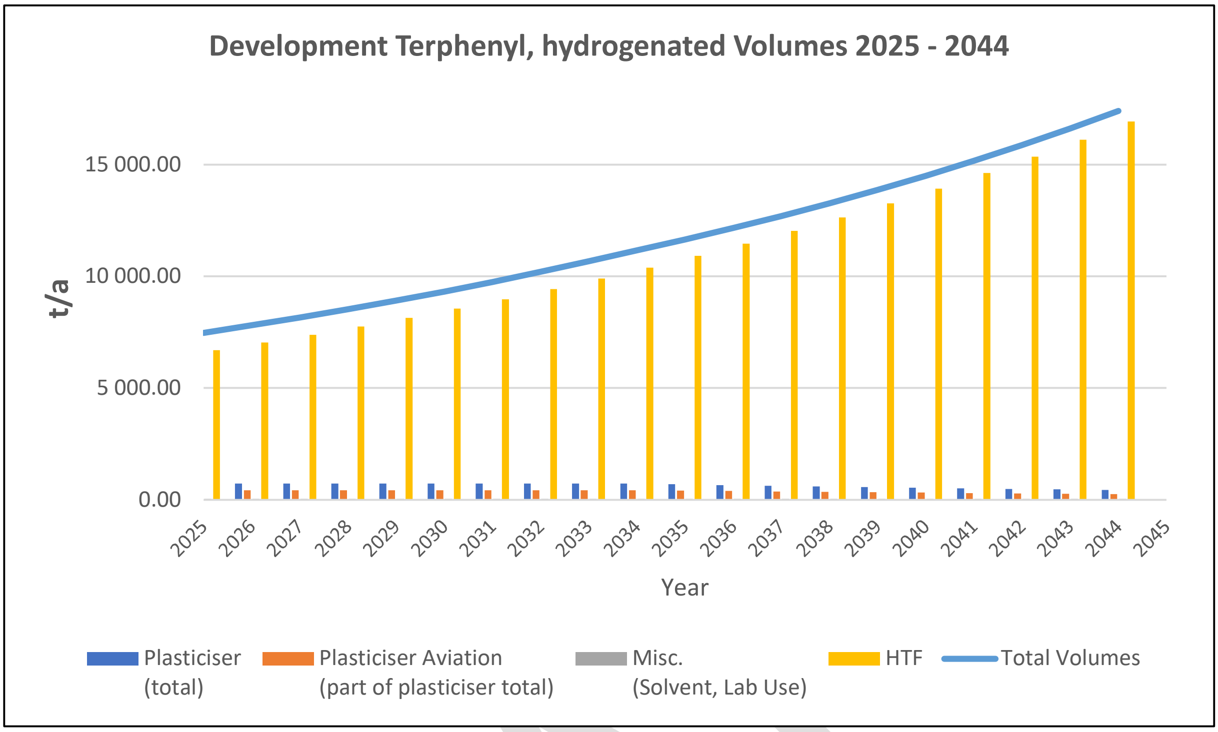
[49] Delivering the European Green Deal | European Commission (europa.eu)
[50] Circular economy action plan (europa.eu)

Figure 29. Estimated trend of volume development of Terphenyl, hydrogenated in the EU from 2025 – 2044



The plasticiser use is assumed to be stagnant from 2025 – 2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. The Dossier Submitter assumes, that due the SVHC listing the reformulation will kick in, resulting in a drop of the plasticiser use in the EU. It is expected that the decrease in volume as of 2036 will be 5% per annum. On the other hand, it is very likely that the production of articles including Terphenyl, hydrogenated as a plasticiser will be relocated outside the EU and that the volume of imported articles containing Terphenyl, hydrogenated into EU will increase. The high number of articles containing Terphenyl, hydrogenated notified to the SCIP Database shows evidence for that. Consequently, for the Baseline Scenario a stagnant plasticiser emission is assumed. The non-HTF and non-plasticiser use is assumed to be stagnant, too.

D.4. Current Releases of Terphenyl, hydrogenated and Baseline Emissions

The current emissions of Terphenyl, hydrogenated to the environment from various sources in 2021 were derived in **Annex B.9.** (Exposure Assessment). The environmental releases are based on the default release factors in accordance with ECHA Guidance R.16. In case other information on the releases was available to the Dossier Submitter and applicable for Terphenyl, hydrogenated, e.g., SpERCs or OECD Emission Scenario Documents, this information was used in preference to the default release factors as indicated in the ECHA Guidance R.16 (ECHA, 2016). Additionally, specific information was collected via the Exposure & Release Questionnaire (Appendix 1 to the Annex) by the LR, which was initiated to update the Exposure Assessment of the Registration Dossier.

The main objective for the approach of the environmental exposure assessment was to present a realistic assessment. The default release factors represent a worst-case approach, overestimating the actual emissions to the environment. Hence, the default release factors give an indication of the relative release potential from the various processes but do not take into account the physico-chemical properties of the substance or any RMM that is used during the process.

Using more specific information, if available, instead of the default release factors guarantees a more realistic exposure assessment, which is based on actual emissions. However, if no other information was available the default release factors as indicated in ECHA Guidance R.16 were used. The default release factors are described in **Table 13**. in **Annex B.9.** (Exposure Assessment).

The share of the total emissions was evaluated based on the market sector and summarised in

Table 67. The exposure assessment shows that in the "high emission scenario" the largest source of Terphenyl, hydrogenated emission to the environment in the EU is attributed to the use in adhesives/sealants. Regarding the high emission scenario, the "use of adhesives and sealants at industrial sites" contribute significantly to the overall emission (approximately 41%). The use of coatings/inks at industrial sites as well as the use as HTF at industrial sites have a share of approximately 25 and 19%, respectively, of the total emissions.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately 67% of the total emissions followed by the industrial use of sealants and adhesives (approximately 14%).

The following market sectors were considered:

- Use in coatings/inks
- Use as HTF
- Use in adhesives/sealants
- Miscellaneous uses (i.e., general formulation, use as solvent and use as laboratory chemical by professionals)

The analysis showed that the adhesives/sealants represent by far the largest share of the total emissions. In the high emission scenario, the share is estimated at approximately 48% whereas the share in the low emission scenario is even higher (approximately 86%).

Table 67. Sources of Emission of Terphenyl, hydrogenated by market sectors

Scenario	**Share of total (%) Low emission scenario**	**Share of total (%) High emission scenario**
Adhesives and sealants	85.76	48.21
Coatings and inks	10.28	25.07
HTF	0.05	19.02
Miscellaneous (general formulation, use as solvent and use as lab chemical by professionals)	3.92	7.71

In **Table 68** the emissions for each compartment (air, water and soil) are displayed. These include the sum of estimated releases to air, water and soil. However, the redistribution in STP is not taken into account for emissions to waste water.

Regarding the low emission scenario approximately the same amount is released to water and soil (approximately 42 and 37%, respectively) whereas the release to air is lower (approximately 22%). For the high emission scenario, approximately 40% is released to air as well as to water. Only approximately 21% is released to soil.

In general, no major route of emission can be determined.

Table 68. Estimated total release for Terphenyl, hydrogenated in EU in 2021

	Estimated EU emissions based on data on volume for 2021

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Environmental compartment	Low (kg per year)	High (kg per year)	Share of total (%)
Air	14 000	710 000	21.64 – 39.80
Water	26 900	706 000	41.58 – 39.57
Soil	23 800	368 000	36.79 – 20.63
All / Total	**64 700**	**1 784 000**	**100**

Table 69 shows the estimated total release for Terphenyl, hydrogenated in EU by market sector in 2021. For the Baseline calculations, the below averaged release shares (average between low and high emission scenario) have been used. The high and low volume emission scenarios were averaged to an estimated Terphenyl, hydrogenated release of 925 t in 2021.

Table 69. Estimated total release for Terphenyl, hydrogenated based on market sector in EU in 2021 based on average release shares and average total volume

Market SU	Release Share (average in%)	Volume of total releases, average (tonnes per year)	Release, average, (tonnes per year)
Plasticiser Adhesives and Sealants	67	**925**	620
Plasticiser Coatings and Inks	18		167
HTF	9		83
Miscellaneous	6		55

This means that the plasticiser applications, representing ca. 10% of the volumes used in the EU are responsible for 85% of the releases of the 2021 volumes. The HTF use, representing 90% of the volume account for approximately 9% of the releases and the remaining non-HTF and non-plasticiser applications (< 1% of the volume used) sum up for 6% of the emissions. In addition, it needs to be considered that Terphenyl, hydrogenated will be entering the EU via articles containing Terphenyl, hydrogenated as a plasticiser and will be released during service life.

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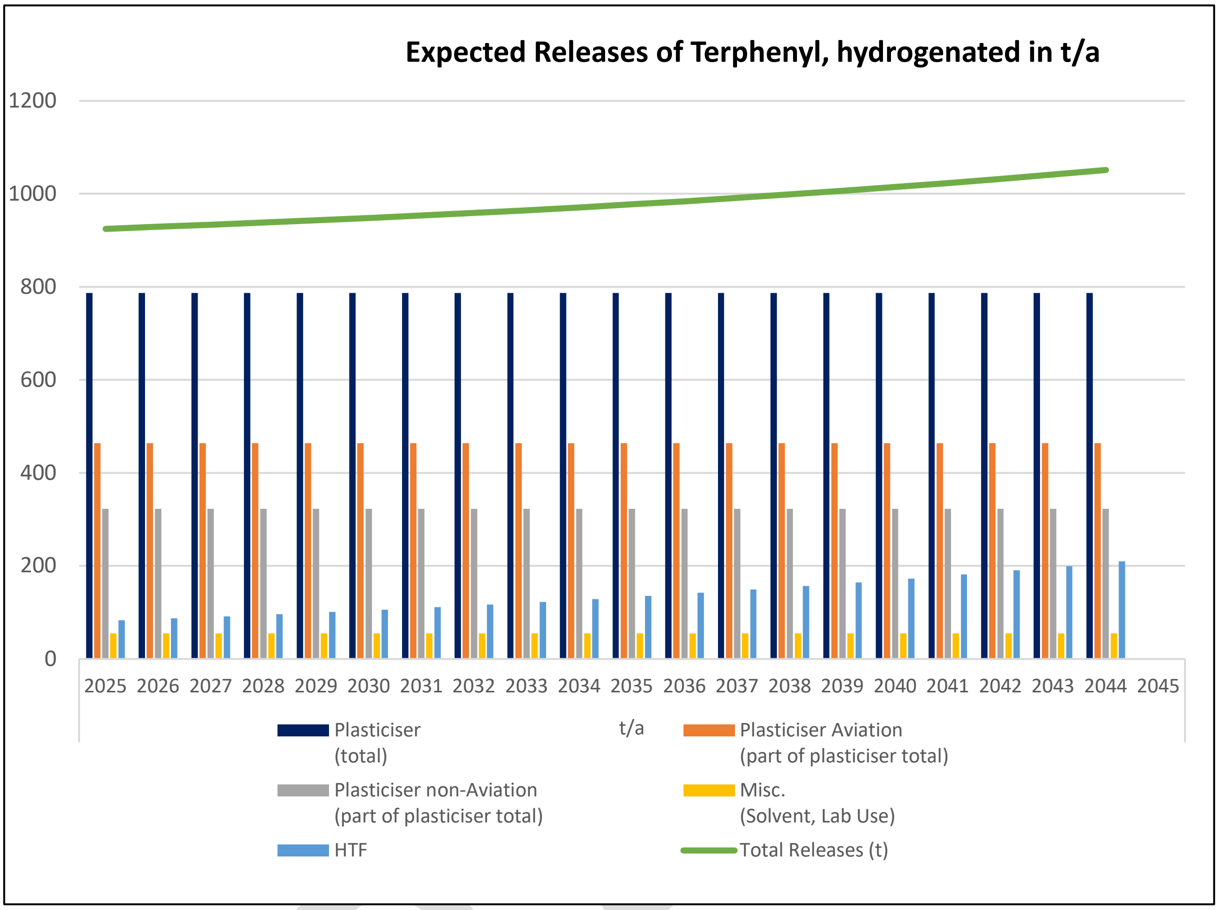
Figure 30. Estimation of expected Terphenyl, hydrogenated releases on an annual basis from 2025 – 2044



The worst-case cumulative releases of Terphenyl, hydrogenated from 2025 to 2044 have been estimated with a total volume of 19 584 tonnes, which corresponds to an average annual release of 979 tonnes. From 2025 to 2044 the annual releases increase from 925 to 1 052 tonnes, as illustrated in **Table 70**.

Table 70. Cumulated and averaged expected releases from 2025 – 2044 per use

	Tonnes per year						
Expected releases	**2025**	**2030**	**2035**	**2040**	**2044**	**Cumulated releases 20 years in tonnes**	**Average annual release in tonnes per year**
Plasticiser (Total)	787	787	787	787	787	15 740	787
Plasticiser Aviation	464	464	464	464	464	9 280	464
Plasticiser non-Aviation	323	323	323	323	323	6 460	323
Miscellaneous (Solvent, Lab. Use)	55	55	55	55	55	1 100	55
HTF	83	106	135	173	210	2 744	137
Total Releases (tonnes)	**925**	**948**	**977**	**1 015**	**1 052**	**19 584**	**979**

Since the emissions from plasticiser uses will be stagnating as outlined before, but the HTF volume is increasing significantly over the next 20 years by a factor of 2.5, the HTF emissions will proportionately increase from 83 tonnes in 2025 to 210 tonnes in 2044, resulting in a doubling of emission share of HTF uses from 9% to ca. 20% of total Terphenyl, hydrogenated emissions. However, it should be noted that this is a very conservative and worst-case approach and most likely a significant overestimation. In particular since on-site exposure measurements (see Chapter B.9.3.3. Exposure measurements) did only identify negligible releases.

Over the examined 20 years, the whole plasticiser releases account on average for ca. 80% of the emissions and the non-HTF uses in sum for 86%. Resulting in a 14% contribution of HTF uses to the total averaged releases.

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Annex E: Impact Assessment

The basis for the impact assessment were mainly the findings and results from stakeholder interactions and responses to questionnaires as well as comments submitted during public consultations (see as well "**Annex G**: Stakeholder Consultation"). Within the public consultations in the SVHC identification and the ECHA prioritization process, a call for information on Socio Economic Impacts by the COM was included. In the framework of this call, the COM asked for submission of information on the possible economic, social, health and environmental impacts (costs and benefits) of possible inclusion into REACH Annex XIV. The questionnaire template is included as Appendix 3.

Comments during the public consultation on ECHA's Draft 10th recommendation were analysed as well, since they mostly include responses on impacts for industry too.[51]

Furthermore, the Dossier Submitter had several telephone interviews with the Lead- and Member Registrants as well as individual users of the substance via its consultant.

In early 2018, the LR of Terphenyl, hydrogenated conducted a simplified socio-economic impact analysis for Terphenyl, hydrogenated, in the context of the process to identify Terphenyl, hydrogenated as SVHC. It was based on responses to a questionnaire (see template in Appendix 2) addressed to their downstream users. 24 completed questionnaires were received from SMEs and large companies, including HTF uses in different industrial sectors (aluminium, polymers, chemicals, ORC) and plasticiser users (sealants, coatings, adhesives). This information was used for the preparation of the Risk Management Option Analysis of the Dossier Submitter in 2020 (ISS, 2021).

In the course of the restriction proposal preparation, the Dossier Submitter launched, between the 21 of June and the 30 of September 2021, a SEA Questionnaire (see template in Appendix 4) to the Terphenyl, hydrogenated value chain, including manufacturers, importers, downstream users, article manufacturers and equipment manufacturers (e.g., boiler makers) via its technical consultant. In addition, some relevant industry associations were contacted. In total about 250 questionnaires were sent and 30 replies were received from different industry sectors.

In summary, 135 responses were analysed for getting a better understanding of impacts for industry and society. **Table 71** is providing an overview.

Several individuals/companies responded to all or some of the requests. Removing duplicate responses leads to a total of 96 individual replies of which 89 are from individual companies and 7 from industry associations.

[51] https://echa.europa.eu/documents/10162/b0b07eaa-b59a-4df5-42d5-cd89ca50e021

Table 71. Responses reviewed related to impacts on industry

Type of Request/Response	Number of Responses
LR - SEA Questionnaire, 2018	24
COM - Socio-Economic Impact Questionnaire, 2020[52, 53]	31
ECHA - Responses to 10th Recommendation, 2020[54]	55
Dossier Submitter - SEA Questionnaire, 2021	29
Total	**139**
Individuals (removing duplicate responses)	96
Individual companies	89
Industry Associations	7

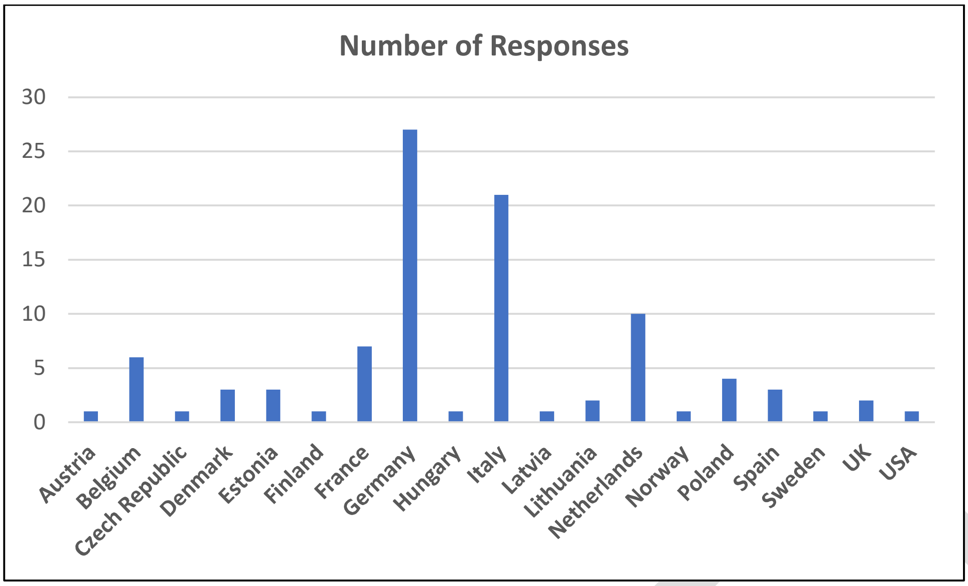
Analysing the number of responses per country it can be determined that unsurprisingly most of the responses came from EU countries, where Terphenyl, hydrogenated has the highest installed base (see **Annex A** – Manufacture and Uses). **Table 72** does show the responses per country and **Figure 31** does illustrate these numbers in a schematic diagram.

Table 72. Responses by Country

Country	No of Responses
Austria	1
Belgium	6
Czech Republic	1
Denmark	3
Estonia	3
Finland	1
France	7
Germany	27
Hungary	1
Italy	21
Latvia	1
Lithuania	2
Netherlands	10
Norway	1
Poland	4
Spain	3
Sweden	1
UK	2
USA	1

[52] Circabc (europa.eu)
[53] Circabc (europa.eu)
[54] https://echa.europa.eu/documents/10162/3cc1642a-cc6d-bc0a-db1b-4d77db6cbd17

Figure 31. Schematic diagram to illustrate the number of responses per country



E.1. Risk Management Options

Information to justify why a restriction is required at EU wide level is provided in **Annex C** (Justification for action on a Union-wide basis). Section E.1 therefore focuses on what the scope of such a restriction might be. In **Annex E.1.1.** three different ROs (RO1, RO2 and RO3) are reviewed, which are included in the SEA. Each of the ROs vary in terms of the scope (and severity of impacts) of the possible restriction.

RO1 presents the proposed restriction which is subject to comments from stakeholders, the Risk Assessment Committee (RAC) and the Committee for Socio-Analysis Committee (SEAC). However, it is important to note that a SEA has also been carried out on RO2 and RO3. Therefore, stakeholders and the two committees can also comment on the proportionality of all three ROs. Further details on all three options can be found in **Annex E.3.** Restriction scenario(s), **Annex E.8.** Proportionality and comparison of ROs, and **Annex F** Assumptions, uncertainties, and sensitivities.

E.1.1. Proposed option(s) for restriction

E.1.1.1. Proposed RO: RO1 – Derogation for HTF Use and Use as Plasticiser in Production of Aircrafts

RO1:

- A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.
- A derogation shall apply for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.
- A derogation shall apply for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts from EiF + 5 years.

E.1.1.2. Justification for the selected scope of the proposed RO

RO1 is the RO with the most balanced scenario between socio-economic impacts and the potential for emission reduction (kg avoided emissions of Terphenyl, hydrogenated). Under RO1 there is a general derogation for HTF use, provided that such sites implement strictly controlled closed systems with technical containment measures to prevent environmental emissions.

These minimum requirements are described under Chapter E. 3.

Exposure measurements on facilities using Terphenyl, hydrogenated as HTFs demonstrated that emissions from HTF plants are negligible (see **Annex B.9.**: Exposure Assessment) if certain design standards are met. Moreover, this substance is critical to many industrial processes and alternatives do not exist for high temperature, non-pressurised HTF applications. The most common alternative substances are expected to have similar vPvB/PBT properties, therefore replacement would result in significant costs and regrettable substitution. Since substitution is not feasible, a ban of Terphenyl, hydrogenated would lead to significant negative socio-economic impacts, potentially resulting in relocation outside of the EU of some industrial users of Terphenyl, hydrogenated.

Furthermore, RO1 includes a derogation for the use of Terphenyl, hydrogenated in plasticisers in the production of aircrafts and their spare parts from EiF + 5 years. Terphenyl, hydrogenated is used in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations for which it was reported that there are currently no alternatives available. Terphenyl, hydrogenated is used due to their ease of application, ease of field repair, flexibility, solvent and chemical resistance, low moisture permeability, and adherence to many metals, composite, and coated substrates. The aerospace industry needs time to develop alternative formulations. To test them against performance requirements, to qualify and validate their use can take several years. It was therefore deemed to be appropriate to provide a derogation for 5 years after EiF. Considering the date of inclusion in the Candidate List in June 2018 and timeline of the restriction process, the overall timeframe for reformulation was > 10 years.

With RO1 it is still expected to reduce the majority of the emissions of Terphenyl, hydrogenated, as the proposed derogation on plasticiser use in the aviation sector is time limited. The analysis and comparison of the ROs in **Annex E.8.** "Proportionality" shows, that RO1 is the most proportionate and cost-effective option and shows, that the need for derogations for both uses is justified.

E.1.1.3. Other RO 1: RO2 – Derogation for HTF Use

RO2:

- A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.
- A derogation shall apply for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

E.1.1.4. Justification for the selected scope of the other RO 1

The socio-economic impact on society would be higher and proportionality is lower compared to RO1. The benefits are clearly outweighing the risks. The costs per kg avoided emissions is not justifying the direct ban on plasticiser uses in the aerospace industry. As outlined under RO1, the aviation sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations has been approved. Therefore, the Practicality (implementability, enforceability, manageability) of this option was considered worse to the proposed option RO1, the transitional period (EiF + 18 months) would not be sufficient for the aviation industry to reformulate.

In addition, it needs to be taken into account, that aerospace supply chains are complex with many actors involved at different levels involving a significant number of SMEs, which increases complexity and timing for substitution.

Monitorability of the restriction is expected to be similar to the proposed restriction RO1. This option **RO2 was overall discarded** as it would be less net beneficial to society than the proposed restriction.

E.1.1.5. Other RO 2: RO3 – Total Ban

RO3:

- A restriction on the manufacture, use and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months

E.1.1.6. Justification for the selected scope of the other RO 2

RO3 is the RO with the highest risk reduction potential and thus the option that would give over long time the highest environmental benefits related to reduced risks associated with the use of Terphenyl, hydrogenated. Under this RO, no derogations would be granted which would mean that all uses of Terphenyl, hydrogenated must cease by the end of the transition period (EiF + 18 months).

The impact on the aviation industry is the same as under RO2. The impact on the HTF sector would be tremendously higher. All ca. 1,300 existing systems using Terphenyl, hydrogenated as HTF in the EU would need to either shut down their plants or retrofit their plants for using alternative HTF (potentially leading to regrettable substitution) or alternative technologies. This would not only result in much higher costs and socio-economic impacts but could as well result in higher emissions, since all plants would need to be emptied and the Terphenyl, hydrogenated waste to be disposed of. The installed volume of about 25 000 t in the EU would become hazardous waste.

Therefore, RO3 was discarded as disproportionate. The Practicality (implementability, enforceability, manageability) of this option is considered the worse of all ROs. Monitorability of the restriction is expected to be worse too, compared to the proposed restriction. It will be difficult to monitor at closed HTF systems, if Terphenyl, hydrogenated has been replaced.

E.1.2. Discarded ROs

Actors or Sectors that would be heavily impacted by a restriction have a vested interest in putting forward evidence that a derogation for their use is needed. Since few stakeholders outside the HTF and Aviation sector provided such information, this would indicate that a restriction on Terphenyl, hydrogenated would not result in disproportionate costs for their uses/sectors.

Therefore, it is concluded that derogations are not needed in any other sectors. ROs with derogations for uses outside the HTF and Aerospace sectors have therefore not been considered. It remains a risk that there are actors with critical uses of Terphenyl, hydrogenated, who did not respond to the stakeholder consultations, but in the absence of any such evidence, increasing the risk to the environment by choosing a more lenient RO is not justified.

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E.1.3. Other Union-wide risk management options than restriction

Terphenyl, hydrogenated itself is not currently regulated by other legislation in the EU. Other EU legislation related to PBT/vPvB substances is mentioned below. This section gives a short description of other Union-wide legislative options that have the potential to influence emissions of Terphenyl, hydrogenated to the environment. In most cases where a concern related to a substance has been identified, there will be several options for addressing this concern. All the additional legislative measures that may be used have different strengths and weaknesses which will vary depending on the case. The Dossier Submitter prepared an Regulatory Management Option Analysis (RMOA) (ISS 2021) on Terphenyl, hydrogenated in 2021, which was discussed at the RIME+ Meeting in October 2020 and submitted to ECHA in 2021[55]. The aim of a systematic analysis of the Regulatory Management Options (RMOs) is to facilitate the identification and choice of the most appropriate measure (or combination of measures) for the case at hand.

The EU CLP Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), does not include the possibility of classifying a substance as PBT/vPvB, since these categories are not part of the GHS. However, the classification 'hazardous for the aquatic environment' includes "ready degradability" and "potential to bioaccumulate" as criteria to consider, meaning that some aspects of persistence are taken into account. Moreover, it is expected that PBT and vPvB properties will be included in the future in CLP.

The EU Water Framework Directive (Directive 2000/60/EC)[56] provides a framework for the protection of inland surface waters, transitional waters, coastal water, and groundwater. The Directive itself does not provide any mechanisms to regulate emissions directly. Local emissions to the environment are controlled by national measures including environmental permits. The Water Framework Directive manages surface water pollutants by identifying and regulating those of greatest concern across the EU known as "Priority Substances" and by requiring Member States to identify substances of national or local concern (river basin specific pollutants). Measures must be taken to reduce the emissions, discharges, and losses of the Priority Substances (PS) and to phase out those deemed the most harmful ("Priority Hazardous Substances" (PHS)). Environmental Quality Standards (EQS) are set in the Environmental Quality Standards Directive (2008/105/EC) for PS and PHS[57].

Member States must ensure that the EQS for the Priority Substances are met in order to achieve "good chemical status" in accordance with Water Framework Directive Article 4 and Annex V 1.4.3. The Priority Substances list was replaced in 2013 via Directive 2013/39/EU, which also includes EQS and other provisions for chemical pollutants. The provisions involve improving the efficiency of monitoring and the clarity of reporting with regard to certain PBT substances. Terphenyl, hydrogenated is not currently identified as a PS or PHS.

The Industrial Emissions Directive (2010/75/EU)[58] establishes the main principles for permitting and control of large industrial installations based on an integrated approach and the application of Best Available Techniques (BAT) to achieve a high level of environmental protection. The manufacture and some uses of Terphenyl, hydrogenated are covered by the Industrial Emissions Directive (IED). However, as no BAT reference documents related to the use of Terphenyl, hydrogenated are available, the IED is considered of limited applicability for the risk management of Terphenyl, hydrogenated.

From an EU policy standpoint, the COM's new Circular Economy Action Plan (European Commission, 2020) announces initiatives along the entire life cycle of products. It targets

[55] Assessment of regulatory needs list - ECHA (europa.eu)
[56] WFD Directive. Consolidated version 20/11/2014. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0060-20141120&qid=1632903621154
[57] http://ec.europa.eu/environment/water/water-dangersub/index.htm
[58] IED Directive. Consolidated version 06/01/2011. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106&qid=1632903943515

their design and promotes circular economy processes to stimulate sustainable consumption. It also aims to ensure that the resources used are kept in the EU economy for as long as possible, thus reducing waste.

The Waste Framework Directive (2008/98/EC)[59] sets out measures addressing the adverse impacts of the generation and management of waste on the environment and human health, and for improving efficient use of resources. An amendment[60] to the Waste Framework Directive prescribes that from 5 January 2021 suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA thus providing waste operators with information about hazardous substances in the waste they are processing. As already mentioned in previous sections, the SCIP Database includes > 12 000 Articles containing Terphenyl, hydrogenated.

In the above mentioned RMOA of the Dossier Submitter, **Authorisation** and Restriction under REACH were compared as potential risk management options (see **Table 73**).

The analysis of Authorisation as RMO – against the key criteria - demonstrates that the Restriction route would be the most appropriate option to deal with the potential risks derived from the manufacture and use of Terphenyl, hydrogenated in the EU. In contrast, authorisation would be a disproportionate, less practical, and less effective provision due to the lack of suitable alternatives for the vast majority of the volume used; and therefore, it should not be selected as a RMO for this substance based on the lack of alternatives and that the investment cycles for heat transfer fluids on industrial sites are extending beyond the typical authorisation review periods granted under REACH.The main use of Terphenyl, hydrogenated in the EU (approximately 90% of the volume) is as a high temperature, non-pressurised HTF. This use takes place in closed systems from which low emissions are, in principle expected. However, situations may arise in which releases could be possible (e.g., top-up, sampling, transport, cleaning and maintenance or final disposal). Because of the properties of Terphenyl, hydrogenated as a vPvB substance, those situations could lead to an unacceptable risk of Terphenyl, hydrogenated reaching environmental compartments. Furthermore, it is not clear whether industry is currently using the best available technologies to guarantee that emissions during normal operations are adequately controlled. For this reason, a restriction could be based around introducing technical requirements to ensure that Terphenyl, hydrogenated is used and handled at industrial settings in an appropriate manner, e.g., via establishing specific technical requirements aimed at granting tight engineering controls on the equipment where Terphenyl, hydrogenated is used.

A restriction could also better address risks derived from other uses that may lead to significantly higher exposure compared to the HTF use. For uses where risk is considered to be unacceptable, a ban on the use of the substance could apply. Finally, it is very likely that articles containing Terphenyl, hydrogenated are imported into the EU (see **Annex A**: Manufacture and Use). In order to avoid that such articles would reach consumers, volumes of Terphenyl, hydrogenated introduced in the Community would be included in the restriction proposal to grant that such articles would not lead to unexpected emissions of Terphenyl, hydrogenated.

Table 73. Comparison of the identified RMO against the key criteria (Source ISS, 2021)

Criterion	**Restriction**	**Authorisation**
Risk Reduction Capacity	++	+

[59] Directive 2008/98/EC. Consolidated version 05/07/2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705&qid=1632904019685
[60] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

Proportionality	++	--
Practicality (implementability, enforceability, manageability)	+	-
Monitorability	+	+
Regulatory Consistency	++	+

E.2. Alternatives

This section identifies and analyses potential alternatives to Terphenyl, hydrogenated in terms of hazards, technical feasibility, economic feasibility, and availability.

Section E.2.1. sets out the functions and corresponding IU of Terphenyl, hydrogenated.

Section E.2.2 presents the different alternative substances to Terphenyl, hydrogenated and the sources of this information.

The assessment of hazards, technical feasibility, economic feasibility, and availability of each alternative are presented in Section E.2.3., whilst the conclusions from the assessment of alternatives are summarised in Section E.2.4.

E.2.1. Description of the use and function of the restricted substance(s)

As mentioned before, ca. 90% of Terphenyl, hydrogenated is used as a HTF, with about 10% of its use being in other applications, such as:

- Additive in plastics (plasticisers);
- Additive in coatings, paints, inks;
- Additive in sealants and adhesive applications;
- Solvent or process medium;
- Laboratory chemicals.

HTFs are used in situations where precise temperature control is needed, such as in the manufacture and processing of synthetic fibres, plastics, rubber, and other chemicals. HTF can be used in non-pressurised or pressurised liquid phase systems. HTFs (or heat transfer media) are of great importance for many industrial processes in which heat needs to be transported or transformed. The most important requirements are:

- low vapor pressure
- high heat capacity
- low viscosity
- high thermal stability and
- low corrosivity

A HTF is a liquid or gas which is specifically manufactured for the transmission of heat. HTFs can be used by many sectors for any single- or multiple-station heat-using system. Thus, they are primarily used as an auxiliary fluid to transfer heat from a heat source to other areas of a process with heat demands. The HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater). Selection of the most suitable HTF is based on the type of industrial applications, stable temperature range for safe operation and lifetime of the HTF. Synthetic HTFs like Terphenyl, hydrogenated do not require pressurizing at temperatures up to 350°C. Another advantage of using a mineral or synthetic fluid, as opposed to water, is that it generally has a lower freezing point. Lastly,

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HTFs also tend to be less reactive and corrosive to pipes and other parts of the system than water.

Synthetic HTF systems allow fuel and energy consumption to be reduced by 20 to 25% compared with steam heating systems, making thermal fluid an efficient solution, both environmentally and economically. In an indirect heating system using steam overall efficiency of 65 – 70% is obtained, i.e., over 30% of the fuel's energy is lost, representing an increase in energy costs and lower efficiency of the heating system. The same process heated with HTF has an efficiency of 90% (Pirobloc, 2021a).

Non-pressurised liquid phase systems are generally the simplest to design and operate. HTFs can be used in this type of system as long as the operating temperature is below its boiling range. When the operating temperature of the HTF is above its boiling range a pressurised system is needed. A pressurised inert gas (nitrogen) is used to maintain HTF in the liquid phase in these systems.

Terphenyl, hydrogenated is specifically used as a HTF in closed manufacturing systems, including those for polymers, waste heat recovery, oil and gas, petrochemicals, and renewable energy. Terphenyl, hydrogenated can be used as an HTF with high operating temperature range of 325-350°C in non-pressurised liquid phase heat transfer systems, because it has a boiling point of 342°C at the standard atmospheric pressure (101.325 kPa). At temperatures above 350°C heat transfer systems containing Terphenyl, hydrogenated need to be pressurised.

E.2.2. Identification of potential alternative substances and techniques fulfilling the function

This section describes the approach to identify, compare, and select potential alternatives to Terphenyl, hydrogenated. The overall goal is to support informed decisions regarding the advantages and disadvantages of different alternatives to Terphenyl, hydrogenated.

The alternative to Terphenyl, hydrogenated would need to be technically and economically feasible, but also have a favourable hazard profile to avoid regrettable substitution and subsequent regulatory action on the alternative. Considering these conditions, this identification process can be divided in three general steps:

- Screening of information sources
- Assessment on the technical suitability of the alternatives
- Assessment of the hazard profile of the alternatives

In the analysis of the second step, the uses of the substance will be considered separately.

E.2.2.1. Screening of information sources

This screening step has mainly consisted in the review of the different information sources in which alternative substances to Terphenyl, hydrogenated are included, such as:

- available literature and bibliography, and
- information from stakeholders and responses to the SEA questionnaires.

Technical documentation on specifications for plant construction[61] identify Terphenyl, hydrogenated, 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS 63231-51-6; EC 400-370-7), and dibenzylbenzene, ar-methyl derivative (CAS 53585-53-8; EC 258-649-2) as possible HTFs (See **Figure 32**).

"The heat transfer media (HTM) will be organic oil, modified terphenyl type. The plant shall be capable of using the following HTM types without compromising on efficiency, plant lifetime and performance:

[61] Polymer Plant Specification (Source: undisclosed Technical Specification of HTF Plant)

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- *Therminol 66 from Solutia* (= Terphenyl, hydrogenated)
- *Dowtherm RP from Dow Chemical* (= 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene)
- *Marlotherm SH from Eastman* (= dibenzylbenzene, ar-methyl derivative)
- *Diphyl R from Lanxess."* (= Terphenyl, hydrogenated)

Figure 32. Polymer Plant Specification for HTF Unit

1.2.2 Process fluid

1.2.2.1 Heat transfer media

The Heat transfer media will be organic oil, modified terphenyl type. The plant shall be capable of using the following HTM types without compromising on efficiency, plant lifetime and performance:

- Therminol 66 from Solutia
- Dowtherm RP from Dow chemical
- Marlotherm SH from Sasol
- Diphyl R from Lanxess

Supply temperature	[°C]	290
Return temperature	[°C]	325

Also, these two substances (Dowtherm RP and Marlotherm SH) were included in the RMOA conducted by the Finnish Safety and Chemicals Agency (Tukes, 2020), the Finnish competent authority regarding REACH, as part of a functional grouping approach for high temperature, non-pressurised HTF, which might be used as substitutes for the SVHC-identified substance Terphenyl, hydrogenated.

In November 2021, the COM published a draft of the proposal for a restriction roadmap under the chemical strategy for sustainability (European Commission, 2021a), which was discussed at the 42nd CARACAL meeting. This roadmap includes an entry in Annex I (Rolling list of (groups of) substances for restriction) related to substances used as high temperature HTFs, that comprises Terphenyl, hydrogenated and these two potential alternatives. Furthermore, in February 2022 the Austrian competent authority published a comment[62] on this restriction roadmap, indicating that they and the Finnish competent authority had established discussions in relation to a possible cooperation for proposing further measures for these two substances. The aim of this action is to ensure an adequate risk reduction measure (possibly a restriction) for these two substances in order to avoid regrettable substitution of Terphenyl, hydrogenated.

In general, HTFs can be classified, according to their chemical structure, in three main types (Pirobloc, 2021b):

- Mineral
- Synthetics
- Silicones

Mineral fluids are obtained from conventional oil refining, in which the base oil is extracted directly from the distillation of petroleum. The majority of these consist of paraffinic and naphthenic hydrocarbons, to which some additives are added to give them properties that improve their performance. The general operating range is around -10°C to 315°C.

Synthetic fluids are obtained via chemical synthesis processes or other processes different to conventional refining. They consist of a benzene-based structure and include diphenyl and

[62] Comment of the Austrian CA on the Restrictions Roadmap: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/d9d35c5f-8c6f-4fe6-98ec-649667c55864/details

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biphenyl oxides, diphenylethanes, dibenzyltoluenes, and terphenyls. The operating temperature range for these types of fluids is around -20°C to 400°C.

Silicone fluids are used in specialised heat transfer applications. In the comparative temperature ranges of the mineral and synthetic fluids, they are unlikely to be choices for most process applications due to performance and cost factor disadvantages.

Based on information obtained from the responses to the SEA questionnaires, the following synthetic fluids could be also considered as potential alternatives to Terphenyl, hydrogenated:

- Benzene, ethylenated, by-products from (CAS 68608-82-2; EC 271-802-8)
- Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl (EC 915-589-8)
- Reaction mass of m-terphenyl and o-terphenyl (EC 904-797-4)
- Diphenyl ether (CAS 101-84-8; EC 202-981-2)
- Biphenyl (CAS 92-52-4; EC 202-163-5)
- Cyclohexylbenzene (CAS 827-52-1; EC 212-572-0)
- Bicyclohexyl (CAS 92-51-3; EC 202-161-4)
- Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS 84961-70-6; EC 284-660-7)
- Benzyltoluene (CAS 27776-01-8; EC 248-654-8)
- Ditolyl ether (CAS 28299-41-4; EC 248-948-6)

It has to be noted that Bicyclohexyl (CAS 92-51-3; EC 202-161-4) is not registered under the REACH Regulation. Therefore, this substance is discarded as alternative to Terphenyl, hydrogenated because it cannot be legally marketed and used in EU in the required quantities (see **Annex A**).

Concerning the substitution of Terphenyl, hydrogenated in the other applications, e.g., in plasticiser uses in plastics, sealants and coatings, only scarce technical information is available to the dossier submitter.

According to the feedback during the Public Consultation on the SVHC Listing in early 2018 (ECHA, 2018b), the Aerospace Industry Association (AIA) commented that "*Terphenyl, hydrogenated is found in most polysulfide sealants. It is used as a high viscosity plasticizer to prevent phase separation of heavy constituents from settling out during storage, often found in accelerators. More importantly, the plasticizer must not fog or leach out of the cured polysulfide sealant once cured and exposed to numerous exposure environments*". According to the response, it will be difficult to replace Terphenyl, hydrogenated "*because the list of plasticizers compatible with polysulfides is limited and some of these can be ruled out as substitutes due to environmental and human health concerns (e.g., some phthalates, chlorinated paraffins). Polysulfide sealants are broadly used in the aerospace and defence industry because they provide flexible and chemically resistant sealing with low moisture permeability. They have excellent resistance to fuels, salt water, ozone and sunlight and exhibit resistance to impact, shock, vibration, and thermal cycling. They provide a secure, long-lasting seal to components which may be exposed to or immersed in liquids for prolonged periods of time. Other uses of Terphenyl, hydrogenated in polysulfides include specialty aerospace sealants for fuel tanks, window installations, sealing sandwich assemblies, self-levelling compounds, hole filling, low density, fast cure sealants, temperature-resistance, fuel, pressure and weather resistance, and pressure and environmental sealants. They are also used in potting compounds for potting of electrical connectors and potting inserts in sandwich panels. They are also found in tapes, electrical insulating coating compounds, epoxies, polyurethane potting and moulding compounds, and electric cables*". The aerospace industry claims, that "*it would be technically challenging to identify and develop equivalent or superior alternatives for these numerous uses of Terphenyl, hydrogenated. There are no direct replacements in many critical applications and replacement would likely involve significant redesign and requalification and recertification activities in this industry*".

A literature search revealed, that recently novel monomeric and oligomeric dibenzoate plasticizers have been introduced. These new plasticizer solutions have been specially tailored for polysulfide sealant applications. They have been found to be high-performing, low-fogging alternatives to traditional chemistries used in polysulfides. Additionally, they are expected to be less hazardous compared to chemistries such as chlorinated paraffins and phthalates. In conclusion, it seems that technical alternatives are available, such as dibenzoates, phthalates or chlorinated paraffins.

It was found in addition, that substitution of Terphenyl, hydrogenated in epoxy-based adhesives is taking place already. Product literature from an adhesives company[63] does demonstrate, that Hydrogenated terphenyls were removed from their products to address global regulatory concerns regarding its vPvB properties. While it's not a regulatory requirement yet, the company is revising the chemistry in many of their hydrogenated terphenyl containing products. A comparison of the formulations via the old[64] and the new[65] safety data sheet of one of the adhesives reveals, that Terphenyl, hydrogenated has been replaced by Diethylene glycol bis(3-aminopropyl) ether (CAS-No. 4246-51-9). According to the website of the company, they are selling into the aviation industry[66,67] but others as well.

Diethylene glycol bis(3-aminopropyl) ether has been REACH-registered in the volume band 100 – 1 000 t/a[68]. The uses include industrial and professional applications in adhesives and coatings. According to PubChem[69] the function of the substance in adhesives and coating can be as plasticiser and viscosity adjustor.

As potential plasticiser substitutes little attention to Orthophthalates was given due to their intrinsic properties. But a more in-depth analysis revealed that there are classes of phthalates, different from Orthophthalates, which are in general less hazardous, such as Isophthalates and Terephthalates. There is an ECHA document on the Assessment of Regulatory Needs (ECHA 2021g) that reports information on this group of phthalates. While for some substances the need for further studies is highlighted, for others the results indicate that, due to the unlikely hazard of these substances, there is currently no need for further EU regulatory risk management.

In conclusion, it seems that technical alternatives are available, such as Diethylene glycol bis(3-aminopropyl) ether, dibenzoates, ortho-, iso- and terephthalates or chlorinated paraffins. However, it is not easy to find out the technical suitability and for which sector (e.g. aviation) in which application these substances could be used.

Considering this fact, the final list of alternatives to be assessed are indicated in **Table 74**:

Table 74. List of alternatives

Alternative	Chemical name	CAS	EC
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene	63231-51-6	400-370-7
2	Dibenzylbenzene, ar-methyl derivative	53585-53-8	258-649-2
3	Benzene, ethylenated, by-products from	68608-82-2	271-802-8
4	Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl	-	915-589-8

[63] https://webaps.ellsworth.com/edl/Actions/?document=50412&language=en
[64] Safety Data Sheet is available to the Dossier Submitter
[65] ResinLab EP1290 Clear Epoxy Adhesive
[66] ResinLab - The Leading Resin Manufacturer
[67] How to Choose a Static Mixer - ResinLab
[68] Registration Dossier - ECHA (europa.eu)
[69] 4,7,10-Trioxa-1,13-tridecanediamine | C10H24N2O3 - PubChem (nih.gov)

5	Reaction mass of m-terphenyl and o-terphenyl	-	904-797-4
6	Diphenyl ether	101-84-8	202-981-2
7	Biphenyl	92-52-4	202-163-5
8	Cyclohexylbenzene	827-52-1	212-572-0
9	Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues	84961-70-6	284-660-7
10	Benzyltoluene	27776-01-8	248-654-8
11	Ditolyl ether	28299-41-4	248-948-6
12	Mineral fluids	-	-
13	Dibenzoates		
14	Orthophthalates	-	-
15	Chlorinated paraffins	-	-
16	Iso- and Terephthalates	-	-
17	Diethylene glycol bis(3-aminopropyl) ether	4246-51-9	224-207-2

E.2.2.2. Assessment on the technical suitability of the alternatives

Regarding the use as HTF, alternatives to Terphenyl, hydrogenated need to have a similar boiling point (342°C) at standard atmospheric pressure (101.325 kPa) to be used without excessive thermal degradation in liquid phase, non-pressurised systems at a high temperature range of 325-350°C. As the working temperature of the non-pressurised liquid phase systems must be below the boiling range of the HTF, substances showing values of the boiling point lower than 325°C cannot be considered suitable technical alternatives to Terphenyl, hydrogenated, because they require the pressurization of the heat transfer system.

Synthetic HTFs generally have higher maximum operating temperatures than mineral fluids based hot oils, which are not recommended to be used above a temperature of 315-320°C (Damiani MR, 1998). Therefore, mineral fluids cannot be considered as alternative to Terphenyl, hydrogenated as HTF for technical reasons.

The boiling point values and the registered uses of the potential alternatives has been obtained from the information of their respective REACH registration dossiers disseminated in the webpage of ECHA (ECHA, 2021e), and from bibliographic sources (in the case of alternatives 12, 13, and 14). These values are described in **Table 75**:

Table 75. Boiling points and registered uses of the potential HTF-alternatives

Alternative	EC	Boling point (°C)	Registered uses
1	400-370-7	335-365	HTF
2	258-649-2	390.1	HTF, plasticiser, etc.
3	271-802-8	265-295	HTF, etc.

4	915-589-8	314	HTF, laboratory chemical, etc.
5	904-797-4	355	HTF
6	202-981-2	258	HTF, solvent or process medium, laboratory chemical, etc.
7	202-163-5	255	HTF, solvent or process medium, laboratory chemical, etc.
8	212-572-0	235	HTF, solvent or process medium, laboratory chemical
9	284-660-7	300.4 - 407.5	HTF, plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, laboratory chemical, etc.
10	248-654-8	283 - 287	HTF, etc.
11	248-948-6	283	HTF, etc.
12	-	-	HTF, etc.

Entry "etc." in the table means that other uses different to the uses defined for Terphenyl, hydrogenated are registered for the substance. In the case of Alternative 1, as there are not uses defined in the REACH registration dossier, the use has been extracted from the SDS of one registrant (Dow, 2017).

All the potential alternatives considered include the use as HTF in the registration dossier.

Alternatives 3, 4, 6, 7, 10 and 11 show values of the boiling point below 325°C and they cannot be considered suitable alternatives to Terphenyl, hydrogenated for technical reasons. This conclusion is aligned with the analysis performed on these substances in the RMOA developed by the Finnish CA (Tukes, 2020). For the same reason Alternative 8, that had not been assessed previously, cannot be considered.

Alternative 9 is a UVCB substance that shows a very wide range for the boiling point (more than 100°C). This is due to the presence of different constituents that make an exact value for this property difficult to predict. For this substance it is expected that some constituents in the lower boiling point range would undergo significant thermal degradation at high temperatures in non-pressurised systems, thus it would not qualify as direct substitution candidate for Terphenyl, hydrogenated in those specific conditions (Tukes, 2020).

On the contrary, Alternatives 1, 2 and 5 could be considered as suitable alternatives to Terphenyl, hydrogenated from the technical point of view, because all of them show values of the boiling point close to or higher than Terphenyl, hydrogenated.

Finally, mineral fluids based hot oils (alternative 12) are not recommended to be used above a temperature of 315-320°C (Damiani MR, 1998). These substances decompose as well disproportionally as well at lower temperatures. Due to the insufficient thermal stability at the temperature required, they are not used above their real limit. Therefore, mineral fluids cannot be considered as alternative to Terphenyl, hydrogenated as HTF for technical reasons. It should be noted that ca. 75% of the annual built HTF systems are based on mineral oils, while just ca. 25% for aromatic fluids (like Terphenyl, hydrogenated), because operating temperatures are too high.

Considering the registered uses of the selected potential alternatives (see **Table 75**), Alternatives 2, 9, 13, 14 and 15 could be used as plasticiser; Alternatives 6, 7, 8 and 9 as solvent or process medium; Alternatives 9, 13, 14 and 15 as additive in adhesive and sealants; Alternatives 4, 6, 7, 8 and 9 as laboratory chemicals; and alternative 9 as additive in coatings, paints, and inks. However, no specific information about these uses has been

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found. It is worth noting, that in the case of Alternative 4 the use as additive in coatings, paints, and inks is a use specifically advised against in its REACH registration dossier.

As a final summary of the technical assessment, and considering all the above reasons, Alternatives 3, 10 and 11 can be discarded as substitutes of Terphenyl, hydrogenated.

E.2.2.3. Assessment of the hazard profile of the alternatives

The hazard profile of the list of potential alternatives will be used to screen out substances that are likely to be the focus of future regulatory actions, such as those with PBT properties or those which are carcinogenic, mutagenic, or toxic for reproduction (CMR), to avoid a situation of regrettable substitution in the selection of alternatives to Terphenyl, hydrogenated. These substances will be eliminated from the list. It is worth noting that the present assessment is based on how substances are classified today and not on any prediction (e.g., based on structure) of hazardous properties that might lead to further designations in the future.

The hazard profile of the potential alternatives has been obtained from the information of their respective REACH registration dossiers disseminated in the webpage of ECHA (ECHA, 2021e), and they are displayed in **Table 76**:

Table 76. Hazard profile of the potential HTF-alternatives

Alternative	EC	Hazard class	PBT properties
1	400-370-7	Aquatic Chronic 1	Under assessment as PBT
2	258-649-2	Asp. Tox. 1, Repr. 1B, Aquatic Chronic 1	Further information relevant for the PBT assessment is necessary
4	915-589-8	Skin Irrit. 2, Asp. Tox. 1, Repr. 2, STOT Rep. Exp. 2, Aquatic Chronic 4	The substance is handled as if it were a PBT/vPvB
5	904-797-4	Aquatic Acute 1, Aquatic Chronic 1	The substance is PBT/vPvB
6	202-981-2	Eye Irrit. 2A, Aquatic Acute 1, Aquatic Chronic 3	The substance is not PBT/vPvB
7	202-163-5	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1	The substance is not PBT/vPvB
8	212-572-0	Asp. Tox. 1, Aquatic Acute 1, Aquatic Chronic 1	The substance is not PBT/vPvB
9	284-660-7	Asp. Tox. 1	Under assessment as PBT

Regarding the CMR classification, Alternatives 2 (Repr. 1B) and 4 (Repr. 2) should be directly discarded because they lead to a regrettable substitution of Terphenyl, hydrogenated.

Considering the PBT properties, the only potential substitute that should be completely discarded is Alternative 5, because it is a declared PBT substance. However, Alternatives 1 and 9 should be considered with caution, because both are currently under assessment as potential PBT substances via the REACH CoRAP[70] process. If this fact were confirmed in the future, the substitution of Terphenyl, hydrogenated by these alternatives would become a regrettable substitution.

[70] Substance Information - ECHA (europa.eu)

However, in general terms, all of the potential alternatives to Terphenyl, hydrogenated are assigned more restrictive hazardous classifications (Terphenyl, hydrogenated is classified as Aquatic Chronic 2). Therefore, regrettable substitution should be a concern in all of these situations.

In the case of orthophthalates and chlorinated paraffins (short chain chlorinated paraffins – SCCP, medium chain chlorinated paraffins – MCCP, and long chain chlorinated paraffins - LCCP), that could be potential substitutes of Terphenyl, hydrogenated as plasticiser and additive in adhesive and sealants from the technical point of view, they carry similar or equivalent concerns to Terphenyl, hydrogenated in terms of their hazard properties and environmental behaviour.

SCCP has been declared as PBT/vPvB substance and it is restricted in the POPs Regulation[71]; a substance evaluation (SEv) confirms the PBT/vPvB concerns of MCCP, that are also currently involved in a restriction proposal; and LCCP may contain significant amounts of MCCP and can therefore be regarded as a PBT/vPvB containing substance. Furthermore, SCCP and MCCP have been included as an SVHC in the candidate list due to its PBT/vPvB properties, and SCCP is a potentially candidate for SVHC qualification. For this reason, they should be discarded as potential alternatives to Terphenyl, hydrogenated.

The most commonly known orthophthalates used in adhesive and sealants are Butyl-Benzyl Phthalate (BBP), Dibutyl Phthalate (DBP), Di-Isononyl Phthalate (DINP), Di-n-Octyl Phthalate (DNOP) and Di-isobutyl Phthalate (DIBP), according to the information published by COM (European Commission, 2021b). BBP, DBP and DIBP are classified as CMR substances (harmonised classification as Repr. 1B); DINP is currently not classified but its harmonised classification as Repr. 1B is under consultation; DNOP is currently not classified, but it has been notified as Repr. 2 in the C&L Inventory by 8 notifiers, however this substance is not registered under REACH and therefore it cannot be used as alternative to Terphenyl, hydrogenated because it cannot be legally marketed and used in EU in the required quantities. In addition, DBP is under assessment as PBT and some co-registrants of DIBP indicate that they consider this substance as PBT. Therefore, these substances should not be considered as potential alternatives to Terphenyl, hydrogenated related to the plasticiser uses.

Related to dibenzoates it needs to be taken into account, that an Assessment of Regulatory Needs has been conducted[72], because some of the substances in this group have reproductive toxicity properties Cat. 1b. Therefore the right compound needs to be selected, since some substances of this group do not carry these properties. Concerning Iso- and Terephthalates an Assessment of Regulatory Needs (ARN) has been conducted too[73]. For some of the substances in these two groups ECHA stated, that no human health or environmental hazards are expected based on the currently available information and that there is currently no need for further regulatory risk management. Diethylene glycol bis(3-aminopropyl) ether is neither classified as CMR Cat 1 nor as a PBT/vPvB substance or meets the equivalent level of concern criteria, so would not be eligible for SVHC classification.

E.2.2.4. Summary and shortlist of alternatives

According to the conclusions from the previous Sections, a universal alternative to Terphenyl, hydrogenated will likely not be available, and selection of any alternative will need to be considered on a use-by-use basis.

[71] Regulation (EU) 2019/1021 on persistent organic pollutants. Consolidated version 15/03/2021: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R1021-20210315&qid=1646858530383

[72] 76e478b2-5533-3114-e175-8d5ee71a5b6b (europa.eu)

[73] d4d52e3a-578d-0944-d1c3-e3b489a7e82c (europa.eu)

Table 77 below presents the shortlist of alternatives for Terphenyl, hydrogenated in their different uses.

Table 77. Potential alternatives to Terphenyl, hydrogenated

Alternative	EC	Potential uses
1	400-370-7	HTF
6	202-981-2	Solvent or process medium, laboratory chemical
7	202-163-5	Solvent or process medium, laboratory chemical
8	212-572-0	Solvent or process medium, laboratory chemical
9	284-660-7	Plasticiser, adhesive and sealants, paints and coatings, inks and toners, solvent or process medium, laboratory chemical
13	Dibenzoates	Plasticiser, adhesive and sealants
16	Iso- and Terephthalates	Plasticiser, adhesive and sealants
17	Diethylene glycol bis(3-aminopropyl) ether (EC 224-207-2)	Plasticiser, adhesive and sealants, additive in coatings, paints, and inks

These functions are independent from each other and as such, some alternatives may be suitable replacements for some uses, but not for others. This is indicated in the following section E.2.3. that discusses the risk reduction, technical and economic feasibility, and availability of these potential alternatives to Terphenyl, hydrogenated.

E.2.3. Risk reduction, technical and economic feasibility, and availability of alternatives

In this section, the most relevant potential alternative substances from Section E.2.2. are shortlisted and assessed in more detail in terms of their hazard, technical and economic feasibility, and availability. Due to the limited available information in the literature and lack of information provided by stakeholders for some of the uses, technical feasibility can only be assessed in terms of proven or confirmed uses of Terphenyl, hydrogenated. It may therefore be the case that some of the uses of Terphenyl, hydrogenated are not covered in this analysis of alternatives.

The following sections, E.2.3.1 – E.2.3.5 detail the technical feasibility of alternatives that have been selected. Each section comprises the following subsections:

- Availability of alternative
- Human health risks related to alternative
- Environment risks related to alternative
- Technical and economic feasibility of alternative
- Other information on alternative
- Conclusions

Since Terphenyl, hydrogenated has been identified as a vPvB substance, quantitative risk characterisation is not appropriate nor meaningful. Therefore, it is not feasible to carry out a risk comparison between Terphenyl, hydrogenated and its alternatives. Instead, a comparison of hazard properties has been used as an indicator of potential regrettable substitutions.

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Short-listed alternatives were assessed qualitatively based on a comparison of available information on hazard profile, including consideration of:

- Hazard classifications notified under CLP
- On-going regulatory assessments

E.2.3.1. Assessment of 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7)

E.2.3.1.1. Availability of 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

The REACH registration tonnage band for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene is marked confidential. Therefore, there are no references to the volume of substance available for the use as HTF (the only use considered for this substance as alternative to Terphenyl, hydrogenated). The available studies on the ECHA Website suggest an EU volume band of 100 – 1.000 tonnes per year. Therefore, it is questionable if the volume on the EU market could be sufficient to cover the HTF uses. According to the OECD Existing Chemicals Database[74], it is considered globally an HPV Chemical. There is currently one active registration (individual submission) for the substance.

E.2.3.1.2. Human health risks related to 1,2,3,4-Tetrahydro-5-(1-phenylethyl) naphthalene

There is no harmonised classification for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7). The ECHA C&L Inventory does not show any entry related to the human health risks, and no human health classification is provided in the industry self-classification.

Therefore, based on this information, the substance seems to present a low hazard to human health.

E.2.3.1.3. Environment risks related to 1,2,3,4-Tetrahydro-5-(1-phenylethyl) naphthalene

There is no harmonised classification for 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS No. 63231-51-6; EC No. 400-370-7). The notified classifications in the ECHA C&L Inventory are summarised below (assessed October 2021):

- Aquatic Chronic 1; H410 — 56 notifications
- Not classified — 55 notifications

The industry self-classification included in the REACH registration dossier is Aquatic Chronic 1 (H410) and Aquatic Acute 1 (H400).

The RMOA conducted by the Finnish CA on this substance (Tukes, 2020) concluded that, according to the available information, this substance fulfils the criteria for PBT according to Article 57(d) of REACH regulation. Due to its functionality, this alternative to Terphenyl, hydrogenated for use as a high-temperature non-pressurised HTF carries similar concerns in terms of its hazard properties and environmental behaviour. However, this alternative has not yet been subject to the same level of scrutiny applied at EU level under REACH compared to Terphenyl, hydrogenated.

As a result of this RMOA, 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene was included by Finland on the ECHA PACT list for RMOA assessments based on PBT concerns. Moreover, the

[74] OECD's Work on Co-operating in the Investigation of High Production Volume Chemicals - Chemical Detailed Results

substance was included in CoRAP for SEv. This evaluation is being performed by the Finnish CA and it is currently under development in order to clarify the PBT/vPvB concern of the substance or one or more of its constituents, therefore further assessment is needed. Due to the data gaps, experimental data (ready biodegradability, simulation testing) is needed to substantiate the persistence. If the substance fulfils the P or vP criterion, then further information on bioaccumulation (e.g., BCF test in aquatic species) and toxicity (e.g., long-term aquatic toxicity testing) potential of the substance may be needed.

E.2.3.1.4. Technical and economic feasibility of 1,2,3,4-Tetrahydro-5-(1-phenyl-ethyl)naphthalene

This substance shows a boiling point range of 335 - 365°C (at 101.3 kPa), very close to the boiling point value of Terphenyl, hydrogenated (342°C) and to the operating temperature range of 325-350°C in non-pressurised liquid phase heat transfer systems. Therefore, it could be a potential alternative to Terphenyl, hydrogenated in the main use as HTF.

The same conclusion was obtained by the Finnish CA in the RMOA on the substance (Tukes, 2020): after an in-depth evaluation of this potential alternative to Terphenyl, hydrogenated the conclusion was that this substance could be used as reliable substitute for Terphenyl, hydrogenated at the whole temperature range of 300-350°C in non-pressurised heat transfer systems.

However, the substitution of Terphenyl, hydrogenated by this substance is not an easy process in technical and economic terms. According to the responses to the to the SEA questionnaires, the costs for structural alteration, replacement, and refill of the current HTF closed loop systems due to the substitution of Terphenyl, hydrogenated by 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene would be up to €120 000-300 000 per company. Furthermore, completely replacing Terphenyl, hydrogenated from existing heat transfer systems would impose significant technical challenges to industry; it is expected that plants should be stopped for 1-2 months in order to undertake substitution, and hundreds of metric tonnes of hazardous waste would be generated that could not be recovered (Terphenyl, hydrogenated is destroyed by incineration). The downtime cost for the temporary plant shutdown and the incineration costs are unknown and would depend on the company. All the above mentioned would trigger a loss of turnover due to Research and Development (R&D) and investment costs related to the substitution process.

E.2.3.1.5. Other information on 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

No other information available.

E.2.3.1.6. Conclusions on 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene

Although the PBT status of this substance is still under assessment, there are well-founded suspicions that this behaviour will be confirmed in the near future (considering its inclusion in the restrictions roadmap and the future actions to be undertaken by the Austrian and Finnish competent authorities, as commented above). This position is aligned with the idea that substances with the same functionalities show similar hazard profiles. Therefore, the substitution of Terphenyl, hydrogenated by 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

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E.2.3.2. Assessment of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

E.2.3.2.1. Availability of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

The REACH registration tonnage band for diphenyl ether is 1,000 – 10,000 tonnes per year. This is a smaller tonnage band than then one registered for Terphenyl, hydrogenated. However, as the uses considered for this substance as alternative to Terphenyl, hydrogenated (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of Terphenyl, hydrogenated used in the EU, this volume could be sufficient to cover these uses.

E.2.3.2.2. Human health risks related to Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

There is no harmonised classification for diphenyl ether (CAS No 101-84-8; EC No 202-981-2). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Eye Irrit. 2; H319 — 1 796 notifications
- Not classified — 12 notifications
- Skin Irrit. 2; H315 — 8 notifications
- STOT SE 3; H335 — 7 notifications
- Acute Tox. 4; H302, H312 — 5 notifications
- Eye Dam. 1; H318 — 3 notifications
- Skin Sens. 1; H317 — 1 notification

The industry self-classification included in the REACH registration dossier for health effects is Eye Irrit. 2 (H319).

Based on the available data the main hazard to human health presented by diphenyl ether are related to eye irritation. However, a dossier evaluation (DEv) is in place for this substance, related with a request of information about mutagenicity, cytogenicity, and developmental toxicity endpoints. These studies should be finished in August 2023.

E.2.3.2.3. Environment risks related to Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

There is no harmonised classification for Diphenyl ether (CAS No 101-84-8; EC No 202-981-2). The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

- Aquatic Chronic 2; H411 — 1 856 notifications
- Aquatic Acute 1; H400 — 206 notifications
- Aquatic Chronic 1; H410 — 124 notifications
- Aquatic Chronic 3; H412 — 72 notifications

The industry self-classification included in the REACH registration dossier for environmental effects is Aquatic Acute 1 (H400) and Aquatic Chronic 3 (H412).

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB. Available evidence on degradation, bioaccumulation potential, and toxicity for diphenyl ether indicates that the screening criteria for persistence (P), as well as the Annex XIII criteria for bioaccumulation potential (B), and toxicity (T) are not met.

E.2.3.2.4. Technical and economic feasibility of Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

According to the available data (NLM, 2021), Diphenyl ether is commonly used as dye carrier (solvent or process medium). This function is also considered for Terphenyl, hydrogenated (GR, 2020).

E.2.3.2.5. Other information on Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

No other information available.

E.2.3.2.6. Conclusions on Diphenyl ether (CAS No 101-84-8; EC No 202-981-2)

Diphenyl ether has been assessed as a potential alternative to Terphenyl, hydrogenated for the use as solvent or process medium. Both materials can be used as textile dyestuff carrier. Available volumes of the substance are sufficient to cover this use. The substance shows low hazards for both human health and environment, and it is not considered a PBT substance. However, the CMR status of this substance is still under assessment. Therefore, if this status is confirmed in the near future, the substitution of Terphenyl, hydrogenated by diphenyl ether could result in regrettable substitution. Furthermore, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

E.2.3.3. Assessment of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

E.2.3.3.1. Availability of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

The REACH registration tonnage band for biphenyl is 1 000 – 10 000 tonnes per year. This is a smaller tonnage band than the one registered for Terphenyl, hydrogenated. However, as the uses considered for this substance as alternative to Terphenyl, hydrogenated (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of Terphenyl, hydrogenated used in the EU, this volume could be sufficient to cover these uses.

E.2.3.3.2. Human health risks related to Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl is classified according to Annex VI, table 3.1 of CLP Regulation (harmonised classification). The classification for health effects is the following: Skin Irrit. 2 (H315), Eye Irrit. 2 (H319) and STOT SE 3 (H335). This classification has been adopted by registrants.

The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Skin Irrit. 2; H315 — 1 199 notifications
- Eye Irrit. 2; H319 — 1 199 notifications
- STOT SE 3; H335 — 1 199 notifications
- Acute Tox. 2; H330 — 446 notifications
- Acute Tox. 3; H331 — 48 notifications
- Asp. Tox. 1; H304 — 18 notifications
- Acute Tox. 4; H302 — 1 notification

Based on the available data the main hazards to human health presented by biphenyl are related to skin, eye, and respiratory irritation.

In 2018 a testing proposal (DEv) was issued by ECHA on this substance, requiring registrants to perform a pre-natal developmental toxicity study. The results were submitted before December 2019. The evaluation is currently concluded and no changes on the classification of the substance has been observed in the last update of the registration dossier (2021). Therefore, it is assumed that the substance does not show any concern related to the potential for adverse effects on fertility or development.

E.2.3.3.3. Environment risks related to Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl is classified according to Annex VI, table 3.1 of CLP Regulation (harmonised classification). The classification for environmental effects is the following: Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). This classification has been adopted by registrants.

The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

- Aquatic Chronic 1; H410 — 1 200 notifications
- Aquatic Acute 1; H400 — 1 150 notifications

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB, because it does not meet any of the P/vP, B/vB, or T criteria. The substance was included in the Community Rolling Action Plan (CoRAP) in 2013 and it was assessed by the Portuguese CA concerning its PBT properties. The conclusion of the SEv was that the substance is not PBT/vPvB.

E.2.3.3.4. Technical and economic feasibility of Biphenyl (CAS No 92-52-4; EC No 202-163-5)

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

According to the bibliography (Danish EPA, 2014; GR, 2020; Sturaro et al., 1995) both biphenyl and Terphenyl, hydrogenated can be used as dye carriers (solvent or process medium) for textiles and copying paper, although this last use has been stopped in the case of Terphenyl, hydrogenated.

E.2.3.3.5. Other information on Biphenyl (CAS No 92-52-4; EC No 202-163-5)

No other information available.

E.2.3.3.6. Conclusions on Biphenyl (CAS No 92-52-4; EC No 202-163-5)

Biphenyl could be a potential alternative to Terphenyl, hydrogenated for its use as solvent or process medium, mainly as textile dyestuff carrier. Available volumes of the substance are sufficient to cover this use. Also, although the substance shows some human health effects and the environmental classification is more restrictive than that of Terphenyl, hydrogenated, biphenyl is not a PBT substance. Therefore, a case for regrettable substitution can be discarded. Feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

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E.2.3.4. Assessment of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

E.2.3.4.1. Availability of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

The REACH registration tonnage band for cyclohexylbenzene is 100 – 1,000 tonnes per year. This is a smaller tonnage band than the one registered for Terphenyl, hydrogenated. Therefore, it is believed that cyclohexylbenzene is not or will not be available in sufficient volumes, even considering that the potential uses as alternative to Terphenyl, hydrogenated (solvent or process medium, and laboratory chemical) represent less than 10% of the volume of Terphenyl, hydrogenated used in the EU.

E.2.3.4.2. Human health risks related to Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

There is no harmonised classification for cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Skin Irrit. 2; H315 50 notifications
- Eye Irrit. 2; H319 47 notifications
- Acute Tox. 4; H302 41 notifications
- Not classified 13 notifications
- Asp. Tox. 1; H304 7 notifications
- STOT RE 2; H373 3 notifications

The industry self-classification included in the REACH registration dossier for health effects is Asp. Tox. 1 (H304).

Based on the self-classification in the registration dossier and on the additional notified classifications to the C&L Inventory, cyclohexylbenzene is assumed to present a generally low hazard to human health.

E.2.3.4.3. Environment risks related to Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

There is no harmonised classification for cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0). The notified classifications in the ECHA C&L Inventory for environmental effects are summarised below (assessed October 2021):

- Aquatic Acute 1; H400 55 notifications
- Aquatic Chronic 1; H410 55 notifications

The industry self-classification included in the REACH registration dossier for environmental effects is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB, because it does not meet the screening criteria for persistency and toxicity, although bioaccumulation criteria could be met.

E.2.3.4.4. Technical and economic feasibility of Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

According to the published data (GMI, 2020), the use of cyclohexylbenzene as solvent plays an important role in different industries, where the substance is highly used as a solvent in plastics, painting, and adhesives.

No information about technical and economic feasibility of this alternative has been reported in the responses to the SEA questionnaires.

One of the main characteristics for an organic substance to be considered a good solvent is its degree of unsaturation. The unsaturated compounds (mostly C=C double bonds) can crosslink (react) with oxygen to form epoxides, which are highly reactive. This crosslinking causes the formation of long chain molecules which are no longer liquid but solid (termed gums or varnishes), decreasing the solvent function of the material. For this reason, the best solvents are organic compounds that show a low unsaturated degree.

The bromine index is a parameter used to estimate the unsaturation degree. It is defined as the fraction of reactive unsaturated compounds in the organic substance, and it is expressed as grams of bromine (Br2) reacted with 100 g of the sample of the material. The lower this index, the better the solvent behaviour of the substance.

According to the technical information published by the producers of solvents (Eastman, 2022a), the bromine index for cyclohexylbenzene[75] (393) is higher than the same parameter for Terphenyl, hydrogenated (290). Therefore, its solvent behaviour will be worse compared to Terphenyl, hydrogenated.

E.2.3.4.5. Other information on Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

No other information available.

E.2.3.4.6. Conclusions on Cyclohexylbenzene (CAS No 827-52-1; EC No 212-572-0)

Cyclohexylbenzene has been assessed as a potential alternative to Terphenyl, hydrogenated for the use as solvent or process medium. Although this substance is not suspected of having PBT properties, it cannot be considered an adequate substitute for Terphenyl, hydrogenated due to technical reasons (high unsaturated degree), and the registered volumes are not sufficient to fully replace Terphenyl, hydrogenated for this function. For this reason, cyclohexylbenzene cannot be considered a suitable alternative for Terphenyl, hydrogenated as a solvent or process medium.

E.2.3.5. Assessment of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

E.2.3.5.1. Availability of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

The REACH registration tonnage band for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues is 10,000 – 100,000 tonnes per year. This tonnage band is identical to the volume registered for Terphenyl, hydrogenated, so it is expected that the substance may cover all the uses as alternative to Terphenyl, hydrogenated: plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical.

[75] According to its SDS (https://ws.eastman.com/ProductCatalogApps/PageControllers/MSDSShow_PC.aspx) cyclohexylbenzene is the main component (90%) of the MCS-2805 product

E.2.3.5.2. Human health risks related to Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

There is no harmonised classification for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7). The notified classifications in the ECHA C&L Inventory for health effects are summarised below (assessed October 2021):

- Not classified: 94 notifications
- Asp. Tox. 1; H304: 89 notifications

The industry self-classification included in the REACH registration dossier for health effects is Asp. Tox. 1 (H304) if the substance shows a kinematic viscosity ≤ 20.5 mm^2/s at 40°C. If this viscosity is higher, then the substance is not classified.

On the basis of self-classification in the registration dossier and the majority of the notified classifications, Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues is assumed to present a generally low hazard to human health.

E.2.3.5.3. Environment risks related to Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

There is no harmonised classification for Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7). The notified classifications in the ECHA C&L Inventory does not show any entry related to the environmental risks, as neither does the registration dossier.

Therefore, based on this information, the substance seems to present a low hazard to environment.

According to the information of the REACH registration dossier, the substance is not considered PBT/vPvB because it does not meet the criteria for toxicity and bioaccumulation, although persistency criteria could be met. The Italian CA launched a PBT assessment for this substance in 2012, that was finally developed under a SEv after the inclusion of the substance in the CoRAP in 2014. The final decision of this SEv was published in June 2016 and it required registrants to perform additional environmental studies (soil simulation and effects on terrestrial organisms), in order to provide ECHA with further information to clarify the PBT concern. The deadline for the submission of the tests results was December 2019. The SEv is still ongoing.

E.2.3.5.4. Technical and economic feasibility of Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues can be used as a secondary plasticizer in vinyl formulations, dielectric fluid, concrete and asphalt release agent, wire rope lubricant and other specialty lubricant applications (Sasol, 2019). These applications are quite different to the functions of Terphenyl, hydrogenated as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical.

According to the responses to the SEA questionaries, Terphenyl, hydrogenated is used as plasticiser in coatings, adhesives, two-component products that are used for sealants, as well as castings for the protection of joints of buried high voltage cables. Furthermore, it is used in the production process of electro-insulating varnishes and resins, and in many formulations of polyurethane systems. But the main application as plasticiser is in adhesives and sealants for the aerospace industry. Due to the particularities of this industrial sector, the substitution of Terphenyl, hydrogenated by alternatives becomes a very long and expensive process. The customer qualification and approval of the alternatives can take several years and involve a

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significant testing demand. In some cases, this process could require investments of more than 100 000 € as R&D costs.

E.2.3.5.5. Other information on Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

No other information available.

E.2.3.5.6. Conclusions on Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues (CAS No 84961-70-6; EC No 284-660-7)

Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues has been assessed as a potential alternative to Terphenyl, hydrogenated for the uses as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical. Available volumes of the substance are sufficient to cover these uses. The substance shows low hazards for both human health and environment. However, the PBT status of this substance is still under assessment. Therefore, if this status is confirmed in the near future, the substitution of Terphenyl, hydrogenated by Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues could become a regrettable substitution. Furthermore, the feasibility of the substitution in technical and economic terms could not be assessed due to the lack of information.

E.2.4. Summary and conclusion from the assessment of alternatives

The assessment of alternatives indicates that there is not a universal alternative to Terphenyl, hydrogenated that covers all the IU of this substance. No alternative has been found for Terphenyl, hydrogenated when used as a HTF, plasticiser, adhesive and sealants, paints and coatings, and ink and toners.

Only one potential alternative has been found for the use as solvent or process medium (biphenyl), mainly as textile dyestuff carrier. It is worth noting that the LR of this substance, which is also the LR of Terphenyl, hydrogenated, is placing on the market biphenyl as process media or solvent in many industries, including chemicals and petrochemicals (Eastman, 2022b). However, the company does not recommend or market Terphenyl, hydrogenated as solvent or process medium (Eastman, 2022c). This is an indication that both substances are not substitutable in this use.

Nevertheless, there is some uncertainty as to whether this alternative would be technically and economically suitable for this application, as no information on the technical and economic feasibility of biphenyl as alternative to Terphenyl, hydrogenated in this use has been reported during the different public consultations on Terphenyl, hydrogenated. On one side, there could be some further technical criteria not fulfilled that cannot be found by looking at the substance properties alone. On the other side, there could also be other costs (e.g., R&D and investments) that might make this potential alternative not viable. The fact that the responses to the SEA questionnaires have not provided specific information on that alternative for this use suggests that this alternative is likely not viable.

It is worth noting that most of the alternatives initially considered in this Section would lead to a regrettable substitution if they were selected as final alternatives to Terphenyl, hydrogenated. Regrettable substitution leads to a non-level playing field in the European chemicals market. When a substance is replaced by another chemical which ultimately leads to equal or higher levels of hazard or risk, the Regulation is introducing a discriminatory factor on the M/Is of the replaced substance, because this leads to a loss of market share in favour of a substitute substance that does not show any advantage in terms of protection to human health or the environment. This in addition undermines the credibility of the regulatory process.

Finally, it should be noted that, in general terms, the responses to the SEA questionnaires on potential alternatives have been very scarce and poor. Since no specific technical and economic data related to the potential alternatives has been provided by the impacted actors, it is assumed that this assessment of alternatives for the functions of Terphenyl, hydrogenated and its conclusions are valid. If impacted actors do not agree with the conclusions, it is strongly recommended that they provide information during the public consultation allowing the Dossier Submitter to revise this analysis and its conclusions.

E.3. Restriction scenario(s)

The restriction scenarios are defined by the anticipated behaviour of affected actors (current downstream users of Terphenyl, hydrogenated) in response to the ROs. All actors will not necessarily react the same way when faced with a restriction, but they will choose amongst the options that are available to them. These so-called behavioural responses must be defined so that they can be included in the SEA in a meaningful way.

The behavioural options deemed most plausible are:

1. **Switch to alternative substances:** This option is only available for the uses for which alternatives are available from the EiF + allowed transition period, where the transition period may vary between uses. Those that can switch to an alternative sooner may gain a greater EU market share (e.g., first mover advantage). If there are no alternatives available at EiF + allowed transition period, production of products depending on Terphenyl, hydrogenated will have to cease. During the downtime, loss of sales, market share and possibly loss of jobs will occur.
2. **Business reallocation outside EEA:** For the users that have customers outside the EU, relocations of their operations is a possible response to a restriction.
3. **Company would abandon business related to Terphenyl, hydrogenated globally:** For users that cannot find an alternative or the cost of transitioning is too high, the remaining option is to cease all production.

The behavioural responses are based on information received from stakeholders through the 2021 SEA questionnaire (Appendix 4).

E.3.1. Use of Terphenyl, hydrogenated as HTF

The three ROs have the following requirements set out for the use of Terphenyl, hydrogenated as HTF:

RO1 and RO2 include a derogation for the use and placing on the market for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

RO3 means a practical ban on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

Since under RO1 and RO2 this use of the substance is allowed at the industrial level, and all the respondents are industrial companies, the behavioural responses of the users have only been analysed considering the application of RO3 (total ban).

Close to two-thirds of the respondents (64.7%) that are using Terphenyl, hydrogenated as HTF answered that they would switch to alternative substances in case of a restriction of Terphenyl, hydrogenated. This result contrasts with the conclusions obtained in the assessment of alternatives (**Annex E.2**), in which, according to the responses of the same companies, an alternative to Terphenyl, hydrogenated as HTF is not currently available. There are three plausible explanations for this:

- The respondents assume that they will be forced to switch to an alternative with the same (or similar) regulatory pressure, that will face the same issues in the close future but that solves the current problem. This is considered to be the most likely explanation.
- The respondents trust that an alternative will appear during EiF + 18 months. Specifically, references to trusting the know-how of the supplier are made, which implies that the respondents may not have a full picture of the possibility to provide a valid alternative to the use of Terphenyl, hydrogenated as a HTF.
- Non-informed alternatives are currently available, that have not been disclosed due to being part of the know-how of the companies. However, while one reply suggests this possibility, no specific details on this option have been provided to verify the validity of potential alternatives.

In fact, 44.8% of the respondents have declared that they are actively looking for alternatives, through the investment in R&D activities. This value is lower than the result obtained to the general question (64.7%) because some Terphenyl, hydrogenated users lack the necessary expertise to perform these activities and they are confident/dependent on the know-how of their suppliers.

The number of respondents that answered that they would relocate the business outside EEA and those that answered that they would abandon the business globally is the same (17.6% in each case).

Considering the behavioural responses received in relation to the different industrial sectors that are using Terphenyl, hydrogenated as HTF in their production process, the proportion is the following:

Table 78. Responses from HTF users related to different industry sectors

Industrial sector	**Switch to alternative substances**	**Business reallocation outside EEA**	**Company would abandon business**
Chemicals	66.7%	20.0%	13.3%
Fuels and petrochemicals	61.5%	15.4%	23.1%
Plastics	100.0%	0	0
Cement	0	0	100%
Steel	100%	0	0
Paints	50%	50%	0
Total	**64.7%**	**17.6%**	**17.6%**

It is interesting to note that all the respondents from the industrial sectors of plastics and steel production would opt for switching to alternative substances, while all the respondents from the industrial sector of cement production would abandon the business related to Terphenyl, hydrogenated globally.

Results obtained from companies dedicated to the chemicals and petrochemicals production sectors, which are the main proportion of respondents, are very similar, with a vast majority of companies opting for switching to alternative substances. Again, it is worth highlighting that it is likely that those that replied that they would switch to an alternative are probably considering other commercially available products based on substances that may have the same properties as Terphenyl, hydrogenated, and which would therefore follow the same regulatory path in the future. This assumption is based on the consideration that, for a substance to be used as a non-pressurised, high temperature HTF, some properties that may be related to PBT consideration are required.

E.3.2. Use of Terphenyl, hydrogenated as Plasticiser in Production of Aircrafts

The three ROs have the following requirements set out for the use of Terphenyl, hydrogenated as plasticiser in the production of aircrafts:

RO1 includes a derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts from EiF + 5 years.

RO2 and RO3 result in the practical ban on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

In this case, the analysis of the behavioural responses has considered all the proposed ROs, because the only difference between RO1 and the total ban (RO2 and RO3) is the implementation timing, which is longer in the first case.

The only respondent that has declared that is producing Terphenyl, hydrogenated for the use as plasticiser answered that the company would switch to alternative substances in case of a restriction of Terphenyl, hydrogenated for this use. In fact, this firm is actively looking for alternatives through their own investment and resources in R&D activities.

Considering the responses to the call for information by the COM on the possible socio-economic consequences of the inclusion of Terphenyl, hydrogenated in the Authorisation List of the most important sectorial associations of the aerospace industry in the EU and USA (public consultation performed on the summer of 2020), the development and qualification of potential alternatives that can meet the strict safety and performance demands required for use in aerospace applications will take many years due to the stringent testing and thorough validation that must take place for every individual application where Terphenyl, hydrogenated is used across an aircraft product.

This position would be interpreted as an implicit acceptance of this industrial sector for the switch to alternatives provided that there is enough time to implement them, and it matches with the answer of the only respondent to the SEA questionnaire for this use of Terphenyl, hydrogenated.

Therefore, the assumed behavioural responses for the use of Terphenyl, hydrogenated as plasticiser in the production of aircrafts are to switch to an alternative by 100%.

E.3.3. Other uses of Terphenyl, hydrogenated

The three ROs have the following requirements set out for all of the other uses of Terphenyl, hydrogenated:

RO1, RO2 and RO3 mean the restriction (total ban) on the manufacture, use, and placing on the market as a substance, in mixtures or in articles in concentrations of > 0.1% w/w from EiF + 18 months.

No respondents of the SEA questionnaire have indicated that a REACH restriction would pose a problem for all of the other uses of Terphenyl, hydrogenated, outside the uses as HTF in industrial premises and as plasticiser in the production of aircrafts. For this reason, no derogations were considered for these uses in the definition of the ROs.

It is therefore also assumed that all of the other uses would be able to transition to alternatives by EiF + 18 months, and the assumed behavioural responses for these uses are to switch to an alternative by 100%.

E.3.4. Definition of the strictly controlled closed systems (SCCS)

RO1 and RO2 include a derogation that shall apply for the use and placing on the market of Terphenyl, hydrogenated for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

This derogation has been proposed in accordance with other restriction proposals in which placing on the market and use of a substance has been permitted when strict operational conditions (OCs) and risk management measures (RMMs) are adopted, as in the case of Decamethylcyclopentasiloxane (D5) when use in closed systems (ECHA, 2019). Although in this case the volumes of Terphenyl, hydrogenated used as HTF cannot be considered low, the lack of suitable alternative substances or technologies that could lead to an overall reduction in the risk and the low proportion of releases to the aquatic compartment, coupled with high socio-economic benefits, make this measure applicable.

The conditions and requirements that a HTF installation shall comply with to be considered as a strictly controlled closed system are defined in **Appendix 5** of this document.

Compliance with **Appendix 5** will be mandatory for all current and future heat transfer systems using Terphenyl, hydrogenated as HTF to comply with the derogation conditions of the HTF use in this restriction.

The general approach described in **Appendix 5** can be applied to other organic HTFs, alike to Terphenyl, hydrogenated, if similar REACH Restrictions are introduced for other HTFs in the future.

Costs for the implementation of SCCS have been obtained during the stakeholder consultations via questionnaires and over telephone. This is illustrated in the Annex of the initial Annex XV Dossier on page 191, Chapter E.4.2. Costs for applying Strictly Controlled Closed Systems (SCCS) were communicated by industry in the range of EUR 10 000 – 30 000. Therefore an average costs of EUR 20 000 was considered, resulting in a total cost for 1 500 plants of EUR 30 Million. We assume that most of the costs is related to organizational matters, rather than structural measures. The feedback from the public consultation on the restriction proposal received is basically confirming this assumption.

Regarding the control of the current installations, most of the systems are compliant with PED. According to the responses to the 2021 SEA questionnaire (Appendix 4), 19 companies have considered PED during design, construction, and operation of the HTF system and 2 companies considered the previous legislation (Directive 97/23/EC) because their sites were constructed before 1997. It means that close to 75% of the respondents are compliant with PED. This Directive requires the initial legalization of the pressure equipment and periodical regulatory inspections. To achieve conformity with PED, the conformity assessment of pressure equipment must be certified by a notified body, which will ensure that the technical and safety conditions of the installation are maintained. The objective of these inspections is to verify that this equipment complies with the mandatory safety conditions. For this purpose, different types of checks, inspections with non-destructive testing, hydrostatic tests, or other substitute tests are carried out.

Furthermore, any chemical facility in the EU needs to have a permit to operate, issued by local, regional, or national Authorities. These competent authorities regularly assess this permit through periodic inspections and audits.

Finally, the two standards cited in **Appendix 5** are national and non-EU-wide, but they constitute the general rules for the plant basic design in all of the EU countries. As an indication of its recognition and use, the German standard DIN 4754-1 was originally issued in 1973 and it has been periodically modified to be adapted to technical progress (the last version is dated 2015).

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All of the above exposed are indicative of the high level of control of this type of installation at present, which will be increased once all the measures described in **Appendix 5** are implemented.

E.4. Economic impacts

Economic impacts are concerned with costs or cost savings comparing the "proposed restriction" scenario with the "baseline" scenario. Economic impacts comprise the net costs to manufacturers, importers, downstream users, distributors, consumers, and society as a whole. "Net costs" should take into account both costs to actors due to a restriction and possible cost savings caused by the transfer to alternatives.

In considering the "costs" in a restriction scenario the question that needs to be evaluated is, what is the amount that society has to pay in terms of the other resources such as labour and capital in order to secure a cleaner environment or improved human health. Therefore, at the most fundamental level, the economic cost of a "restriction" scenario is the value to society of these other resources that are used up in order to implement it. This is counted as a cost because the resources that are used up are then not available for other purposes. Economic impacts include for example:

- Cost of new equipment or production process necessary to comply with the proposed restriction or ceasing use of equipment and facilities before the end of their intended life;
- Operation and maintenance costs (labour costs, energy costs, etc.);
- Cost differences between different substances due to different production costs and purchase prices of the substances as well as R&D costs (substitution costs);
- Cost differences due to differences under the scenarios (due to reduced or improved efficiency for example)
- Changes in transport costs;
- Design, monitoring, training, and regulatory costs.

As the ultimate focus of a socio-economic impact assessment is to determine the costs (and benefits) to society of a "restriction" scenario, an important aspect of the cost calculation process is the distinction between private and social costs. Therefore, the starting point for assessing the costs to society of a "restriction" scenario is usually to look at the impact on those particular groups or sectors affected. The costs incurred by a particular sector or group as a result of a "restriction" scenario are called the private costs. By contrast, the social costs are the costs of a policy to society as a whole – from an EU perspective this includes all 27 Member States, although costs to non-EU members need to be reflected, as relevant. These subjects are discussed in **Annex E.6**.

The costs of the three ROs (RO1, RO2 and RO3) are estimated based on the behavioural assumptions set out in E.3. and the responses received from the different stakeholder consultations, plus information obtained via literature searches.

Due to the assumptions made and the uncertainty related to them, the investment costs have not been presented as equivalent annual costs (EAC), using a discount rate. EAC is a process whereby non-recurrent (e.g., capital, plant down-time) costs of a measure are equalised over its lifetime using the relevant discount rate.

Because of the expected increase in economic impacts from RO1 to RO3, the impact analysis will start with most severe option, which is RO3.

E.4.1. Economic Impacts of RO3

E.4.1.1. Substitution and Investment Costs

Substitution costs are defined as including both - any one-off or recurring costs directly associated with the substitution process, including R&D costs, investments, cost of raw materials (e.g., chemicals, water, and other input materials) and energy costs. Information on substitution costs, required investments and alternatives were obtained during the stakeholder consultations.

As outlined in **Annex E.3.** for the **Plasticiser Uses,** a switch to alternative substances is most likely. However, no information on potential alternative substances could be obtained since substitution investigations have not started by industry and Terphenyl, hydrogenated was identified as important to extremely important substance by all respondents. It was mentioned that phthalates could be used but are not an option due to similar intrinsic environmental issues. Checking on Online-Sales platforms[76] for chemicals prices, chemical costs ranging from 5€ – 8€ per kg Terphenyl, hydrogenated could be revealed. Since those sellers are mostly located in China it can be assumed, that the costs in the EU will be ranging between 6-10 € per kg, with an average value of 8€ per kg. Surveying the costs for benzoate or phthalate-based plasticiser, the Dossier Submitter assumes that the price range will be very similar. It is therefore supposed that there are **no additional cost for the chemical substitutes** and that due to lack of information load levels and performance for alternatives are comparable.

However, stakeholders from the aviation industry commented, that replacement of Terphenyl, hydrogenated in such sealant and adhesive formulations and the wide range of applications and parts that they are used on within the aerospace and defence industry is not trivial and would be costly and prolonged. In order to meet the extreme demands of the conditions in which these sealants and adhesives operate, these products must be resistant to water, salt, fog, fuels, oils, hydraulic fluids, and other chemicals. They must also maintain flexibility over a wide range of temperatures and be able to adhere to a wide range of substrates. There are also requirements that these products need to meet in terms of processability such as the density, cure time, pot life and miscibility.

The replacement is an iterative process and the time to develop alternative formulations, test them against performance requirements, qualify and validate their use can take many years depending on the specific use of a material and component.

If the performance of the article made with the alternative is equivalent, the OEM needs to work with the airworthiness authority to certify that the changes do not impact vehicle performance. Failure to meet or exceed the technical requirements will likely not be approved by the authority. For structural applications, validation may require additional full-scale demonstration article testing. Given the complex natures of these products, supply chains can be very long and involve several levels of different companies, some large and some small, who are all responsible for supplying each other.

One stakeholder provided a cost estimate of **R&D costs** of **100 000 €.** From the consultation process it can be assumed, that about 20 companies are preparing the formulations for the plasticiser use. Only one actor mentioned that if the use of Terphenyl, hydrogenated is restricted, he would cease its business. The Dossier Submitter therefore assumes that at least 10 companies are supplying the aviation industry would substitute Terphenyl, hydrogenated in their formulations, resulting in an estimated **R&D cost of 1 000 000 €** (10 x 100 000 €) in total.

Beside R&D costs, transitioning to alternatives is usually associated with **investment costs** (e.g., changes in the production process) unless the alternative is a known drop-in alternative. In the case of Terphenyl, hydrogenated on information received from stakeholders it is clear

[76] Alibaba.com, Lookchem.com

that there are no drop-in alternatives available. It is therefore reasonable to assume that investment costs will be incurred, such as costs for purchasing equipment and installation costs for this equipment. However, because the plasticiser applications are reformulations only, the investment costs will be limited. The Dossier Submitter therefore assumes a total **investment cost** of **1 Million €** for the formulators (10 x 100 000 €).

Additional operational costs may also contribute to the overall costs. Nonetheless, since no information has been found related to other operational costs and lack of information provided by the stakeholders, it was not possible to quantify these other potential costs.

The aviation sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations in order to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations have been approved. The re-approval will result in the issuance of a **Supplemental Type Certificate** (STC)[77], change approval or repair approval[78,79]. Related costs and fees depend on the STC type, the airplane and as well the workload for the ECHA and the COM. Some costs can be seen in the COM Implementing Regulation (EU) 2019/2153 of 16 December 2019 on the fees and charges levied by the EU Aviation Safety Agency[80].

However, since the type of needed STC is not clear for the Dossier Submitter, an amount of **1 Million €** is assumed for **aviation re-approval** of introducing new materials.

For the **non-aviation plasticiser uses and the other uses** (e.g., solvents, corrosion inhibitors) no information was provided at all by the stakeholders. Therefore, the same cost range is assumed with the exception of the STC re-approval costs.

Regarding the **HTF Use**, about 2/3 of the stakeholders replied that they would switch to alternatives and the remaining respondents said, they are abandoning the business (17%) or reallocate outside of the EU (17%). However, it is worth highlighting that it is likely that those that replied switching to an alternative are probably considering the other two commercially available products that may have the same or similar properties as Terphenyl, hydrogenated (vPvB or PBT), and which would therefore follow the same regulatory path in the future. This assumption is based on the consideration that, for a substance to be used as a non-pressurised, high temperature HTF, some properties which are related to PBT consideration are unavoidable (see **Annex E.2.** – Alternatives). The Dossier Submitter therefore assumes, that 25% would cease business in the EU (in particular SMEs), 25% would reallocate their business outside of the EU and 50% of the users would switch to alternative substances or to alternative technologies. It is assumed that in total 25% would substitute Terphenyl, hydrogenated with substances, which do not have the required thermal stability and therefore need replacement every 2-4 years due to the high degradation rate (instead of 20 years for Terphenyl, hydrogenated). 25% would switch to alternative heating system - like steam - which would carry very high investment costs. As shown in **Annex A** (Manufacture & Use) there are about1 500 plants using Terphenyl, hydrogenated as HTF. It is assumed that 25% (375 sites) of the total sites would:

- Case 1: relocate to non-EU
- Case 2: abandon business in the EU
- Case 3: switch to alternative HTFs with lower thermostability
- Case 4: switch to alternative technologies, such as steam heating systems.

Related to Case 1, business relocation will likely happen by the larger companies with flexibility in their production location. Regarding the costs associated with the set-up of new plants in non-EU, no information was provided via the stakeholder consultations. According

77 Supplemental Type Certificates | EASA (europa.eu)
78 2c27ddcc-dd0c-49e3-85ba-fa64b0813775 (europa.eu)
79 Registry of restriction intentions until outcome - ECHA (europa.eu)
80 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R2153&from=EN

to Lemmens (2016)[81] a medium-size ORC plant will cost about 400 000 – 500 000 €. A large size PET manufacturing plant with manufacturing capacity of several hundred-thousand tonnes will likely cost several hundred million €.[82] If only 10 million € as an average value will be allocated for the 375 plants assumed to relocate outside of the EU, an investment amount of 3.75 Billion would be the result. The dismantling and disposal costs of the old plants[83] will be considered under Case 2.

Most of the ORC plants would need to close their business according to Case 2, since their temperature window is very tight and only high temperature HTFs will work. Moreover, ORC plants are mostly run by SMEs and connected to the region. This would have a negative impact on renewable energy targets under the EU Green Deal activities related to clean energy production to address climate change, as the energy generated from ORC plants is considered renewable.

Dismantling and disposal costs for abandoned plants are considered to be 250 000 € per site based on different case studies[84,85,86], amounting for Cases 1 and 2 in a cost position of 750 plants x 250 000 € = **187.5 million €**.

Regarding Case 3, mineral oils would be used because the two other high-temperature alternatives[87] are not available as substitutes due to their PBT properties. The costs of a mineral oil is estimated to be about 50% less (= 4 € per kg) but the replacement frequency in the plant would be at least 5-times higher. In the considered 20 years' timeline from 2025-2049, the complete filling needs to be replaced at least 4-times, resulting in a 2-times higher costs for HTF fluids based on mineral oil. Presuming, that the expected 375 plants would as well represent 25% (= 6 250 t) of the total installed volume, the following chemical costs would occur:

- Complete refill costs = 6 250 € x 4 000 € = **25 Million €**
- 2-times exchange of degraded HTF = 6 250 € x 4 000 € x 2 = **50 Million €**

The refill and exchange costs do not include **cleaning and rinsing procedure** at the sites. An additional cost of 10 000 € was reported per site summing up to an additional amount of **750 000 €.**

In addition, existing material in plants would need to be disposed of as waste, disposal costs of all installed volume would be resulting after the ban of Terphenyl, hydrogenated in 2025, adding-up in a total cost of 25 000 t x 250 € = for thermal **disposal** of **6.25 Million €.** Disposal costs were obtained from the literature[88] and via personal communication with hazardous waste handlers.

Due to the fact, that these "alternative" substances are not drop-in alternatives and would require re-design and modifications of the plants, investment costs would be necessary. During the stakeholder consultations investment costs between 0.1-10 Million € were reported per installation. Assuming an average value of 1 Million € per site, **retrofitting costs** of 375 x 1 Million. € = **375 Million €** would occur.

It needs to be noted, that due to the retrofitting of the concerned plants, **downtime** during shutdown of the plants will be needed. Respondents reported between 1 month and 12 months and loss of revenue between **2 Million € - 100 Million €**. Assuming an average value of 5 Million € loss in revenue per site (not considering potential market share loss), a cost of 375 x 5 Million € = **1 875 Million €** would result.

[81] Energies | Free Full-Text | Cost Engineering Techniques and Their Applicability for Cost Estimation of Organic Rankine Cycle Systems (mdpi.com)
[82] Indorama to Build New PET Resin Manufacturing Plant (powderbulksolids.com)
[83] Plant Decommissioning- How to decontaminate, dismantle and decommission process plants | Abhisam
[84] 1857c756-b264-49a6-bca7-9283b59fc0cf (sc.gov)
[85] Case Studies – Technical Demolition Services (tdsinternational.co)
[86] Demolition & Decommissioning Case Studies - EWMI
[87] 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene and dibenzylbenzene, ar-methyl derivative
[88] Baar-Ebenhausen: Preiserhöhung bei der GSB - 42 Millionen Euro Investitionen in die Technik - 206000 Tonnen Sonderabfall im Jahr 2019 angeliefert (donaukurier.de)

In addition, R&D costs in a range of 10 000 – 20 000 € were reported by industry, HTF users would mostly rely on the suppliers to provide an adequate alternative since R&D on utility substances is not really in the scope of their R&D work. Assuming 10 000 € of **R&D Costs** for 375 plant result in an additional cost of **3.75 Million €**.

Moreover, several respondents reported that alternative substances not meeting the high temperature range will result in a reduced performance, lower efficiency, and loss of yield. Since no numbers were provided, only an assumed **loss in efficiency** of 25 000 € per installation (which is a relatively low number) would result in a total additional cost of **€ 9.37 Million.**

Case 4 represents the complete switch from classical organic fluids to high pressure vapour phase (e.g., steam) systems. This complete exchange of equipment would require significant capital investment to modify process furnace systems and other process equipment. Steam pressures of 130 bar or more might be required, which would need serious operational and safety measures. Costs for rebuilding the plant excluding downtime were reported in ranges of 10 – 50 Million €. Assuming only a value of 10 Million € will result in an amount of **3 750 Million €** if 375 plants will switch to **alternative technologies**.

Any changes in operational and maintenance costs for all cases were not considered because no information was available to the Dossier Submitter.

There are likely additional costs, which were not considered but could have a significant impact, in particular on the HTF sector. Terphenyl, hydrogenated and Biphenyl (CAS 90-43-7) are co-produced in the same chemical reaction. The yield or conversion rate per substance is described in the literature with generally 50/50[89,90]. Biphenyl is used as a component in HTFs in Solar Systems. In case of a ban of Terphenyl, hydrogenated it is likely, that manufacturing of biphenyl is not competitive anymore. However, since Terphenyl, hydrogenated is not manufactured in the EU and no details are available, no cost estimations could be included.

Table 79 summarises the Substitution Costs for RO3. In total about 10 Billion € could result from the substitution. More than 99% of the costs are associated to the HTF use, mostly allocated to investment costs.

Table 79. Substitution and Investment Costs for RO3

Type of Substitution Costs	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Chemical Costs	0	0	50
R&D Costs	1	1	3.75
Re-Approval Costs	1	0	0
Disposal Costs Installed Volume	0	0	6.25
Cleaning & Rinsing	0	0	0.75
Downtime during Retrofitting	0	0	1 875
Refill	0	0	25
Investment and Retrofitting	1	1	375
Investment: Installation of new Technologies	0	0	3 750

[89] 40 - FINAL REPORT - Biphenyl LOUS - 2014 11 04 (windows.net)
[90] CN103804114A - Method for preparing hydrogenated terphenyl - Google Patents

Investment: Installation of new Plants in non-EU	0	0	3 750
Investment: Decommissioning & Disposal	0	0	187.50
Loss in efficiency and yield	0	0	9.37
Subtotal	**3**	**2**	**10 032.62**
Total Sum (Million €)	**10 037.62**		

E.4.1.2. Cost of loss in profits and reduced EU production

If companies have to reduce their EU production and sales of products temporarily or permanently on Terphenyl, hydrogenated, there will be associated profit losses, which are considered as costs to society. The "sales at risks" are represented by substances and products for which a reduction in sales as a result of a restriction on Terphenyl, hydrogenated are most likely.

The total Terphenyl, hydrogenated volume sold in the EU by importers and manufacturers of the substance in the HTF use is according to **Annex A** (Manufacture and Use) 6 700 tonnes per year. Allocating a Terphenyl, hydrogenated cost of 8 000 € per tonnes would result in a loss of revenue of 53.6 Million € per year. Considering the 20 years period under review (2025 – 2049) would result in a loss of 1 072 Million € in revenue for the HTF market. Considering a common gross margin of 25%, the profit loss amounts in total to 268 Million €.

The common gross margin of 25% chosen for the HTF market is higher than the 10% one chosen in the proposed restriction for DP (ECHA, 2021d). The Dossier Submitter considers that DP is a commodity chemical. For a commodity chemical a gross margin of 10% is justifiable. However, Terphenyl, hydrogenated is considered to be a highly specialised utility chemical. For specialty chemicals gross margins between 20–30% are typical. Therefore, the value of 25% was taken.

The US Chemical Manufacturing Industry Gross Profit grew by 19.08% in 2 Q 2022, which led to improvement in Chemical Manufacturing Industry's Gross Margin to 25.52%[91]. Other sources provide average gross margins of even > 50%[92]. We therefore assume that the value selected is balanced.

The profit loss for the plasticiser uses in the aviation industry accounts for 17.2 Million € (430 tonnes per year x 8 000 € x 20 x 0.25) assuming as well a margin of 25%. The profit loss for the non-aviation plasticiser uses and the remaining other uses is assumed to be 13.62 Million € (340.5 tonnes per year x 8 000 € x 20 x 0.25). In summary, a total profit loss for the prohibited sales of Terphenyl, hydrogenated in the amount 298.82 Million € can be noted with a conventional calculation method.

Estimating the profit losses for the downstream industry is more difficult. Due to a very similar scenario in the Restriction Proposal by Norway for the substance DP (ECHA, 2021d), where the flame retardant is used in the aviation industry, the same approach was taken. The substance is used in the aviation Industry as a flame retardant in electrical & electronic equipment, such as wire & cable plastic coatings, coil bobbins, cable straps, switches, small electronic appliances, and computers (motherboards, chargers, and hard-plastic connectors).

For DP a "profit at risk" for the aviation industry of 41 Million € per year was estimated (see **Annex E.4.3.**) in the Restriction Proposal for a total ban. Basis for the calculations were the revenues for the PRODCOM Codes 22299180 (Plastic parts for aircraft and spacecraft) and

[91] Chemical Manufacturing Industry Profitability by quarter, Gross, Operating and Net Margin from 2 Q 2022 (csimarket.com)
[92] Chemicals And Allied Products: industry financial ratios benchmarking (readyratios.com)

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29311000 (Insulated ignition wiring sets and other wiring sets of a kind used in vehicles, aircraft, or ships). Since the latter is cross-sectoral, only 10% of this Code was allocated to aircraft. PRODCOM (PRODucts of the European COMmunity) is a EU wide survey of production mainly for the manufacturing industries collected under Council Regulation (EEC) No 3924/91 and provides statistics on the production of manufactured goods carried out by enterprises on the national territory of the reporting countries. PRODCOM is available via the Eurostat Webpage[93]. Since PRODCOM does not provide information on profit margins, Norway used older data (2003 – 2007) from Eurostat used for this purpose (a profit margin of 10.1% was used). Since the scenario for Terphenyl, hydrogenated in the use as plasticiser in the Aviation industry is alike, a total profit loss of 820 Million € could be taken into account (41 Million € per year x 20 years).

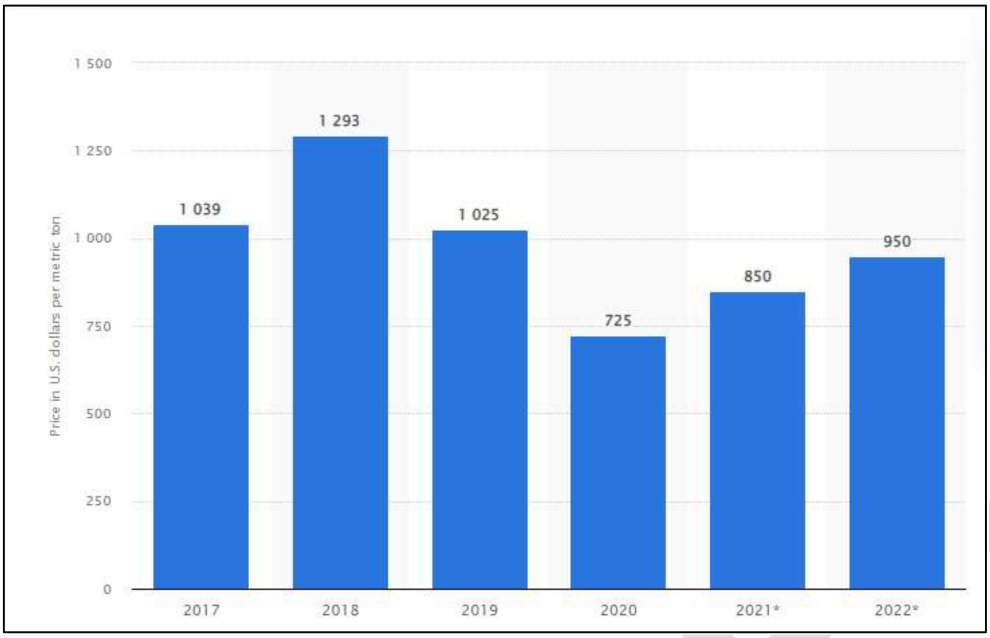
Regarding the profit losses of the downstream users of HTF applications, in particular the PET industry was very concerned. The PET business is already exposed to imports from Asia and Middle East as it is a commodity polymer resin. Already about 1 Million tonnes per year are imported into EU and the EU PET industry needs to produce against import parity pricing, which sets the upper limit on sales price and the EU cost structure is already above the Asian one. This puts an additional margin squeeze on industry. Global PET players have already many locations outside EEA. Furthermore, a reduction in plant capacities of PET commodity resins would also impact upstream industry for the monomers production, like terephthalic acid and ethylene glycol in the EU. A gradual disappearance of PET industry in the EEA would also deteriorate capability in (chemically) recycling plastics, in particular as PET is one of the best recyclable plastics available the EU.

The EU PET market is 3.5 Million tonnes per year (2019), of which 1 Million tonnes is imported from third countries. The PET costs per tonne are ranging between 850 and 950 USD (see **Figure 33**), which corresponds to 750 – 850 € per tonnes. Assuming a profit margin of 10% and a loss of 25% sold EU volume (625 000 tonnes per year) due to site closures, relocation outside EU and competitiveness reasons, a loss in profit from EU-based material of about 531 Million € could occur for 20 years (625 000 t x 850 € x 10% = 53.12 Million € x 20 years = 1 062.4 Million €).

It is reasonable to assume that for all other HTF uses, a similar loss in profits will result, therefore a revenue loss of 2 125 Million € for all DU HTF applications could be estimated by conventional method.

[93] Overview - Prodcom - statistics by product - Eurostat (europa.eu)

Figure 33. Price of PET worldwide from 2017 to 2020 with estimated figures for 2021 and 2022, in US $ per metric ton (Source: Statista 2022)



However, applying the SEAC approach when changing to an alternative published in a paper agreed at SEAC 52[94] the profit loss is significantly lower by assuming that profit loss experienced by firms subject to restriction (or authorisation) will be offset after a period by profit gains made by firms who produce or supply alternatives to the substances subject to restriction (or authorisation). The offset occurs only after a period as it is assumed that firms supplying alternatives will need some time to respond to the regulation and increase their output. The effect of this assumption is to reduce the period over which profit losses are assumed to occur. The SEAC paper provides some discussion of the factors which might affect how long the "period before offset" should be assumed to last. The starting points are described as follows:

- For SAGA cases: 2 years of profit losses (average of 3 years for tangible assets and 1.2 years for intangible assets, rounded to the nearest year).
- For no-SAGA cases: 4 years of profit losses (average of 5 years for tangible assets and 2.4 years for intangible assets, rounded to the nearest year).

"SAGA" here means "suitable alternative(s) generally available", a concept which relates specifically to the authorisation context. However, the SEAC paper indicates that these starting points can be used also "where relevant" in restriction cases also.

The assumption made for the revised profit loss estimate is that, if the dossier indicates that there is a drop-in alternative available, or that firms can be expected to adjust to the restriction relatively quickly, then this is equivalent to a "SAGA" case and two years' worth of profit would be lost through the restriction. Where no drop-in substitute appears to be available and it would seem to take firms longer to adjust to the restriction, it is assumed the non-SAGA situation applies, and four years' worth of profit loss is counted.

In R01, a derogation is provided to the aviation sector to give additional time to substitute – it is assumed that this effectively changes the assumption from one of "no drop-in substitute" to "drop-in substitute". Finally, the dossier assumes that downstream users of non-aviation plasticisers and "other uses" would be able to substitute easily and would suffer no profit loss. If downstream users can adjust easily, it seems logical to assume that the suppliers of the

[94] Microsoft Word - AFA_SEAC_SurplusLoss_SEAC-52.docx (europa.eu)

alternative could adjust easily too. Hence it is assumed in this case that profit losses can be offset completely and no net profit loss occurs.

The overview below summarises these assumptions.

- Aviation plasticiser: no drop-in substitute
- Non-aviation plasticiser: 100% offset
- HTF: no drop-in substitute

Downstream User sales outside the aviation and HTF sectors are not considered to be at risk, as it is assumed that the lack of input from stakeholders during the public consultation indicates that the restriction is not likely to pose an issue for other potential uses of Terphenyl, hydrogenated, and it is therefore expected that all other uses can be substituted before the end of the transition period by 2025 (EiF + 18 months). As shown in **Table 80**, the revised total "**profit at risk**" is estimated with **617.52 Million €.**

Table 80. Summary of loss in profits and reduced EU production of RO3

Type of Lost Profits	**Plasticiser Use Aviation**	**Non-Aviation Plasticiser and Other Uses**	**HTF Use**
	in Million €		
Sales of Terphenyl, hydrogenated by Importers and Manufacturers	1,72	0.00	26.80
Downstream User Sales	164.00	0.00	425.00
Subtotal	165.72	0.00	451.80
Total	**617.52**		

E.4.1.3. Enforcement Costs (compliance costs)

Enforcement costs are administrative costs incurred by Member States National Enforcement Authorities (NEAs) to ensure that actors on the EU27 and EEA30 market comply with the EU regulations. By evaluating data reported from European studies on inspection and enforcement costs of REACH restrictions (Milieu, 2012[95]; RPA, 2012[96]), ECHA assessed the administrative burden of enforcement for new restriction proposals. ECHA concluded that based on data reported by Member States, the average administrative cost of enforcing a restriction is approximately 55,000 € per year for all EEA Member States. Assuming constant administrative costs of enforcement over the time horizon under consideration (2025 – 2045), the value of **compliance costs** over 20 years is **1.1 Million €** for EEA30 (55 000 € x x 20 years). This estimate is assumed to be relevant for all ROs in the same way. The 1.1Million. € have been distributed equally over the 3 different uses, resulting in a cost of 0.37 Mio € for each use.

It is worth noting that the Netherlands used the same value in their Restriction Proposal on PAH in granules and mulches used in infill materials[97]. For the purpose of the current

[95] report_study8.pdf (europa.eu)
[96] report_study11a.pdf (europa.eu)
[97] Registry of restriction intentions until outcome - ECHA (europa.eu)

assessment, the value of 55 000 € per year should be seen as only illustrative in terms of the potential order of magnitude of the cost.

E.4.1.4. Summary of Costs for RO3

The estimated **total costs for RO3 are in the range of 13.3 Billion €.** Around 93% are allocated to the use as HTF, followed by about 6.4% by the plasticiser use in aviation. The costs on the non-aviation plasticiser uses and the remaining uses (e.g., solvents) are contributing insignificantly with below 0.5%. **Table 81** provides the summary of the costs.

Table 81. Total costs for RO3

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in Million €		
Substitution and Investment	3	2	10 032.62
Profit Losses	837.2	13.62	2 393.00
Enforcement costs	11	11	11
Subtotals	851.2	26.62	12 436.62
% of Total costs	6.39	0.20	93.41
Total Sum	**13 314.44**		

E.4.2. Economic Impacts of RO2

The difference between RO3 and RO2 is, that there is a derogation in place for all HTF uses. Consequently, the costs for all non-HTF uses remain the same, since these applications will be prohibited as of 2025.

Most of the costs of the HTF use will be taken out, except for enforcement costs and costs related to structural and organisational (e.g., inspections, training) improvements of the plants, as needed. The derogation will apply, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions. During the stakeholder consultations costs for those improvements were communicated with 10 000 – 30 000 €. For the Dossier Submitter it is reasonable to assume, that for the 1 500 plants using Terphenyl, hydrogenated an average cost of 20 000 € would apply, resulting in a total cost of **30 Million €**. The on-site measurements conducted in several HTF plants (see **Annex B.9.**) demonstrated, that most had these strictly controlled closed systems in place and potentially only training is needed. In addition, the enforcement costs will be applicable to the HTF uses, since the implementation of e.g., containment and training measures should be inspected as well. In comparison to RO3, the total costs of RO2 have been significantly reduced to an amount of about **201.82 Million €**. The cost contribution of HTF uses is now at about 15% and the majority of the costs is carried by the Aviation plasticiser use (>80%). The remaining uses carry about 1%. **Table 82** is summarizing the costs for RO2.

Assumptions made for the profit losses are as follows:

- Aviation plasticiser: no drop-in substitute

- Non-aviation plasticiser: 100% offset
- HTF: permanent derogation

Table 82. Total costs for RO2

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use
	in Million €		
Substitution and Investment	3.00	2.00	30.00
Profit Losses	165,72	0.00	0.00
Enforcement costs	0.37	0.37	0.37
Subtotals	169.09	2.37	30.37
% of Total costs	83,78	1.17	15.05
Total Sum	**918.82**		

E.4.3. Economic Impacts of RO1

Regarding RO1, the costs for the HTF use and the "Non-Aviation Plasticiser" and "Other Uses" remain the same as compared to RO2. Because the aviation plasticiser use will receive a derogation for 5 years (2025 – 2029), the loss in sales of Terphenyl, hydrogenated from their manufacturers and importers to formulators of sealants and adhesives will be reduced.

As a **profit loss ca. 83 Million €** was taken into account for the aviation supply chain, derived according to the aforementioned SEAC paper on evaluating profit losses. The Dossier Submitter believes that this is a worst-case consideration and potentially an overestimation, because the 5 years derogation (after EIF) should have provided most actors in this industry sufficient time to substitute the use of Terphenyl, hydrogenated as plasticiser in the aviation sector. Terphenyl, hydrogenated was included in the Candidate List in June 2018[98], thus providing more than 10 years of time for reformulation and re-certification (Supplemental Type Certificates). The aviation industry would carry more than 70% of the costs, followed by the HTF use (ca. 25%) and around 2% by the remaining uses.

Assumptions made for the profit losses are as follows:

- Aviation plasticiser: drop-in substitute (via derogation)
- Non-aviation plasticiser: 100% offset
- HTF: permanent derogation

Table 83 summarises the costs for RO1.

Table 83. Total costs for RO1

Type of Costs	Plasticiser Use Aviation	Non-Aviation Plasticiser and Other Uses	HTF Use

[98] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

	in Million €		
Substitution and Investment	3.00	2.00	30.00
Profit Losses	82,86	0.00	0.00
Enforcement costs	0.37	0.37	0.37
Subtotals	86.23	2.37	30.37
% of Total costs	72.48	1.99	25.53
Total Sum	**118.96**		

E.4.4. Cost Comparison of ROs

The table below (**Table 84**) compares the costs for the different ROs to the Baseline Scenario. It is not surprising that RO3 shows the highest cost, since it is the most severe RO. The amount of RO3 is 90-times higher than RO1 and 50-times higher than RO2. Substitution and investment costs in RO3 account for >90%. In RO2 and RO1 there is a shift towards profit losses, with share of >80% for both Ros, especially at the expense of the aviation industry.

Table 84. Comparison of total costs for RO1 – RO3 relating to the Baseline

Type of Costs	**RO1**	**RO2**	**RO3**
	in Million €		
Substitution & Investment	35.00	35.00	10 037.62
Profit Losses	82.86	165.72	617.52
Enforcement costs	1.10	1.10	1.10
Total Costs (in Million €)	**118.96**	**201.82**	**10 656.24**

Eastman Chemical has announced[99] to invest up to 1 billion US$ in a material-to-material molecular recycling facility in France to recycle up to 160 000 tonnes annually of hard-to-recycle plastic waste that is currently being incinerated. The plant and an innovation centre would be expected to be operational by 2025, creating employment for approximately 350 people and leading to an additional 1 500 indirect jobs in infrastructure and energy. The most suitable and efficient technology would be based on Terphenyl, hydrogenated as HTF. The economic impacts of this project have not been evaluated and included in the calculation but could add additional costs to RO3 if technology based on Terphenyl, hydrogenated would not be available.

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[99] Our Announcement in France | Molecular Recycling | Eastman

E.5. Risk reduction capacity

E.5.1. Benefits to the environment and human health

In 2018 Terphenyl, hydrogenated was identified as a substance meeting the criteria of Article 57 (e) as a substance which is vPvB, in accordance with the criteria and provisions set out in Annex XIII of REACH. Terphenyl, hydrogenated is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**).

The ECHA Guidance for PBT/vPvB assessment (Chapter R.11) (ECHA, 2017) states: "Experience with PBT/vPvB substances has shown that they can give rise to specific concerns that may arise due to their potential to accumulate in parts of the environment and

- that the effects of such accumulation are unpredictable in the long-term;
- such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in substance concentration".

Another aspect of the vPvB concern important to consider is the political objective to phase out the use of vPvB substances, see for example the recent COM Chemicals Strategy for Sustainability towards a Toxic-Free environment[100]. Furthermore, Recital 70 of the REACH Regulation states that exposure of the environment and humans from substances of very high concern should be reduced as much as possible.

In the case of Terphenyl, hydrogenated, it has been demonstrated via monitoring of environmental emissions from HTF systems that air emissions are very unlikely to occur, however spills and leakages may result in accumulation of (low) amounts of Terphenyl, hydrogenated in soil. It is estimated that other uses have a greater impact to the release of Terphenyl, hydrogenated to the environment, such as the use in coatings, adhesives, or sealants (See **Annex D**).

E.5.2. Emission reductions as a proxy for potential benefits

Quantification of risks is currently not possible for PBT or vPvB substances, which makes quantification of benefits challenging.

Moreover, for these substances a full cost-benefit assessment is usually not feasible due to their specific properties. Decisions on PBT measures appear to be rarely motivated explicitly by arguments of C/E. IVM (2015)[101] reported there is a wide "grey zone" between EUR 1 000 and EUR 50 000 per kg PBT emission avoided.

However, the potential benefits will be linked to the environmental stock and therefore also reduction in emissions. SEAC[102] is advising the use of emission reductions, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, as a proxy for potential future benefits (ECHA, 2008).

For Terphenyl, hydrogenated, factors which may indicate additional concern beyond the vPvB properties include professional uses and service life of articles manufactured with Terphenyl, hydrogenated (see **Annex A.2**). These uses may result in exposure of Terphenyl, hydrogenated to parts of the population as well as to the environment. Combined with the vPvB properties, this can lead to significant impacts not likely for uses related to localised emissions and exposure only.

[100] https://ec.europa.eu/environment/strategy/chemicals-strategy_es
[101] Institute for Environmental Studies (2015): Benchmark development for the proportionality assessment of PBT and vPvB substance. Report R-15/11.
[102] Committee for Socio Economic Analysis. Committee for Socio-Economic Analysis - ECHA (europa.eu)

As recommended by SEAC (ECHA, 2014), a cost-effectiveness (C/E) analysis approach was followed, using emission reductions as a proxy for benefits. The advantage of this approach is the total emission reduction associated with the implementation of a restriction is independent from the timing of the reduction, as long as they fall within the analytical period considered.

E.5.3. Changes in emissions

Contrary to the economic impacts, the expected emission reduction that can be achieved under each restriction scenario will not be affected by the behavioural responses to the restrictions. The reason for this is that the restriction sets out when manufacture and use must cease, and the emissions of Terphenyl, hydrogenated will cease accordingly (however, effects of emissions from articles in which Terphenyl, hydrogenated has been used need to be taken into account). There is a possibility that some actors using Terphenyl, hydrogenated as plasticiser will switch voluntarily to alternatives before entry into force. However, this was not considered in the emission estimations.

As described in the baseline scenario of Terphenyl, hydrogenated in **Annex D.3**, the continued use of Terphenyl, hydrogenated was estimated as illustrated in **Figure 30**. It should be noted that emissions prior to 2025 were not considered. Furthermore, the model assumes that emissions ceases when the use of Terphenyl, hydrogenated is banded for a certain use. In reality, parts of the emissions particularly for the use as plasticiser will occur during the service life of the articles including Terphenyl, hydrogenated and thus, after the ban is in force. A significant share of the emissions occur at the end-of-life stage. Furthermore, if the use as HTF is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (ca. 25 000 tonnes in approximately 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis. Therefore, the reduction in emissions compared to the baseline will in reality be spread over the entire analysis period (2025- 2044), which is not shown in the following figures.

Figure 34 illustrates the trend of expected emissions for RO 1 where a derogation exists for plasticiser uses in the aviation industry (5 years after entry into force) and a general derogation for HTF uses, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

Since the HTF emissions are likely to be an overestimate as mentioned before, the introduction of controlled closed systems with engineered containment measures to minimise environmental emissions was considered with an emission reduction of 75% compared to the baseline scenario.

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Figure 34. Expected releases of Terphenyl, hydrogenated for RO1

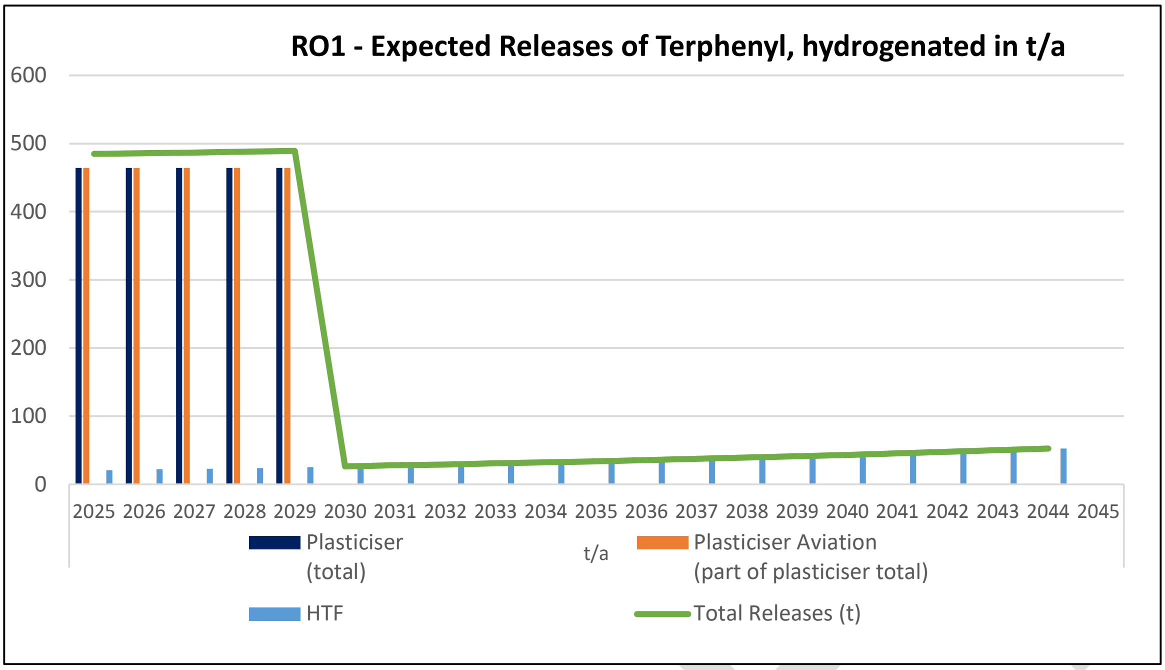
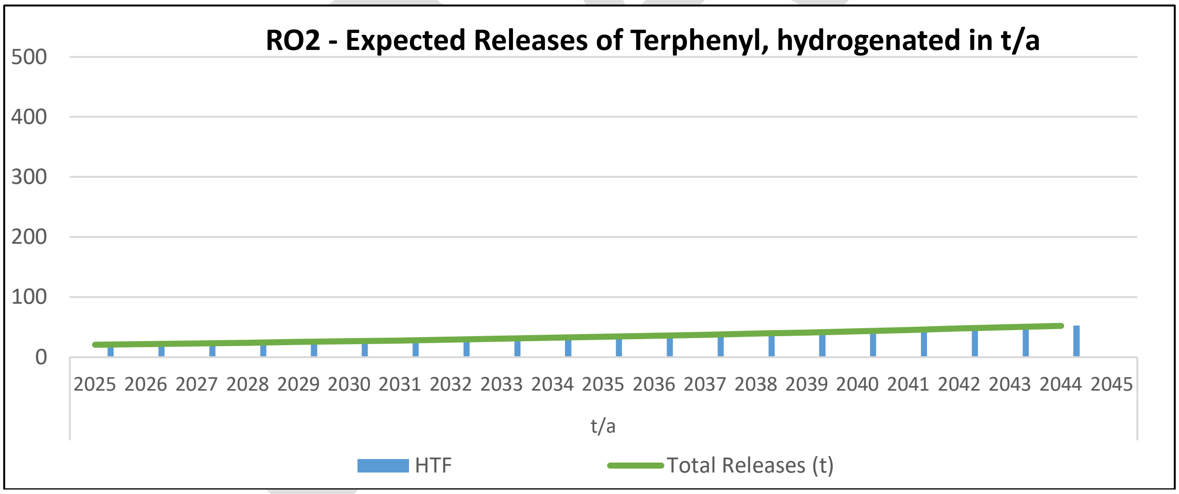


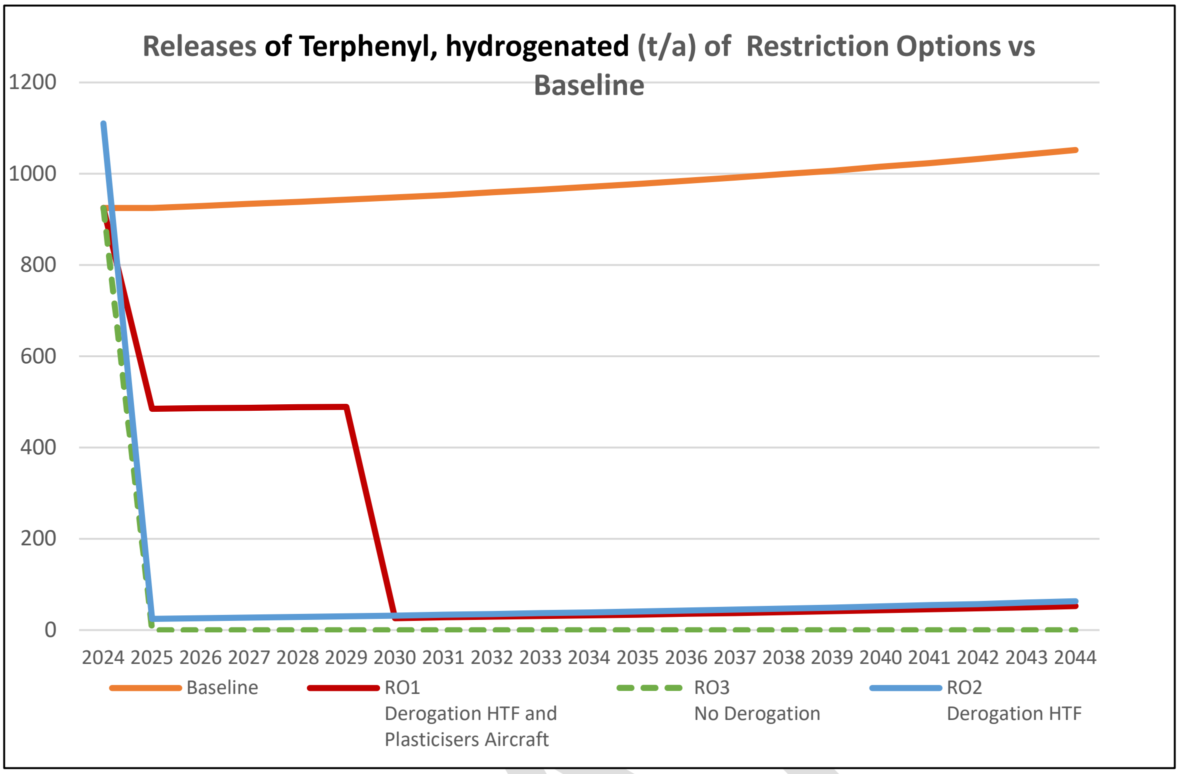
Figure 35 shows the expected releases for RO2, where the derogation exists only for the use of Terphenyl, hydrogenated as HTF. Consequently, emissions will only arise from the use of HTF.

Figure 35. Expected releases of Terphenyl, hydrogenated for RO2



In case of RO3 where no derogations exist, all emissions will cease in 2025. **Figure 36** does exhibit the expected emissions of each RO in comparison to the baseline scenario.

Figure 36. Expected emissions of each RO in comparison to the baseline scenario



The overall emission reduction capacity of each RO was estimated by calculating the total emission (incl. all uses) under each scenario with reference to the total emissions under the baseline scenario (= 100%). Consequently, the abovementioned inaccuracies in the timing of the emission reductions have less impact on the emission reduction capacities of the ROs. The longer the time period used for the analysis, the more accurate the total emission reductions.

As the average annual emission reductions are estimated by dividing the total emissions by the number of years in the analysis period (20 years), the same uncertainties as for the total emission reductions also apply to the annual estimates. The expected achievable emission reductions for each RO are presented in **Table 85**, based on the total release quantities of all uses.

Table 85. Emission reduction capacity of all ROs

	Total Emissions (tonnes)	**Total Emissions (%)**	**Emission Reduction Capacity (%)**
Baseline	19 584	100	0
RO1	3 006	15	85
RO2	686	3,5	96.5
RO3	0	0	100

As expected, the most stringent RO (RO3) with a complete ban of Terphenyl, hydrogenated as of 2025 has the highest emission reduction capacity. However, RO1 and RO2 are both very effective and lead to high emission reductions between 85% - 96.5% of the baseline emissions. It is important to note that both ROs include a continuation of HTF use.

Due to the high number of entries of articles containing Terphenyl, hydrogenated in the SCIP database (> 12,000, see **Annex A**), the question was raised if a restriction of imported articles with Terphenyl, hydrogenated content of greater than 0.1% w/w is considered sufficient to adequately address the concerns or if the restriction should cover concentrations as well < 0.1%, since REACH Article 7(2) on "Notification Requirements", Article 33 on "Supply Chain Communication" and the "SCIP Notifications" do not apply. This is an uncertainty since it is not clear, how many articles with concentration levels < 0.1% of Terphenyl, hydrogenated are being imported and if those imported articles would pose a risk of environmental exposure.

E.6. Other impacts

E.6.1. Social impacts

Societal impacts are impacts that may affect workers, consumers, and the general public that are not covered under health, environmental or economic impacts (ECHA, 2008), including employment, working conditions, job satisfaction, and education of workers and social security. Depending on the RO selected for Terphenyl, hydrogenated, societal impacts may vary significantly. A complete restriction leading to a practical ban of all uses of Terphenyl, hydrogenated (RO3) would have a significant impact down the supply chain, particularly related to potential job losses in many industries that rely on Terphenyl, hydrogenated as an HTF. In contrast, RO1 would allow the continued use of Terphenyl, hydrogenated in this application (provided operations are undertaken under certain containment measures) and therefore the impact would be limited.

E.6.1.1. Employment

In many cases, it will be difficult to obtain quantitative information on employment impacts, especially on specific issues such as different occupational groups (in particular without direct consultation with industry representatives and trade associations).

Impacts on EU employment are closely linked to what extent there might be any potential production stops or any permanent closure of production and relocation of production outside the EU under each restriction scenario.

Via the stakeholder consultation process, some numbers were provided by the HTF industry, which allows at least a qualitative/semi-quantitative assessment to calculate lost jobs. In total, 4 147 potential jobs at risk were reported. As described under **Annex E.4.1.1.** (Substitution and Investment Costs under RO3) it is assumed, that 25% of the HTF users (375 sites) would relocate to non-EU and another 25% (375 sites) would abandon business in the EU. Assuming, that 50% of the 4 147 jobs at risk would be lost, the **lost jobs** in the EU's **HTF industry** using Terphenyl, hydrogenated would be **2 074**.

Regarding employment in the Aviation plasticisers use, the Dossier submitter wants to refer again to the work done under the Restriction Proposal of DP by Norway (see **Annex E.6.1.1**., Table 112 of DP Restriction Proposal – ECHA, 2021d). The share of the relevant jobs at risk under the restriction scenarios was assumed proportional to the share of profits at risk. Since the same profits at risk numbers were taken for Terphenyl, hydrogenated, it is reasonable to reference as well to the lost jobs. The relevant jobs associated with the use of DP has been assessed with ca. 10 000. Under a full ban of the substance, Norway assumes that approximately 15% jobs are at risk for the use in aviation. The Dossier Submitter assumes, that for the Terphenyl, hydrogenated use as plasticiser in the **aviation industry** due to its complex value chain, ca. **1 500 jobs could be lost** for a total Terphenyl, hydrogenated ban.

Putting the lost revenues of the "**non-aviation plasticiser and other uses**" into perspective with the aviation plasticiser use, the percentage is ca. 1.6%. This would result in ca**. 24 lost jobs**.

For RO1 it is assume, that 50% of the formulators in the aviation plasticiser industry will be able to reformulate until the restrictions enter into force, so that the lost jobs will be reduced to half, which means 750 lost jobs would occur.

According to the SEA guidance (ECHA, 2008)[103], the total societal value of a job loss is "around 2.7 times the annual pre-displacement wages". Since the number of jobs at risk in the various Member States is not known, the average annual gross salary in the EU is reported at € 24 700[104] for 2018. Therefore, an average annual gross salary of 25 000 € was used. The resulting average annual jobs at risk and their net present value over the analytical period (2025 – 2044) are shown in **Table 86**. The Societal Loss was calculated by the number of lost jobs, multiplied by 2.7.. The SEAC paper on the costs of unemployment[105] agreed on the 32nd SEAC Meeting describes how the various components of the costs of unemployment – lost output, leisure time, scarring etc – can be calculated, based on a methodology set out by Dubourg (2016).[106] This methodology recognises that unemployment is generally a temporary phenomenon, reflecting the time it takes for labour resources to be reallocated from one use to another. The methodology is based on an explicit consideration of how long each source of impact of unemployment is likely to last. The SEAC paper reviews the results presented by Dubourg (2016) to propose a "rule of thumb", whereby the costs of one person being made unemployed is approximated by a figure equal to 2.7 times the previous gross wage of the individual. This rule of thumb is assumed to cover all of the costs associated with unemployment, until the person involved is re-employed.

Table 86. Number of jobs at risk and their value in Million €

Sector	RO1		RO2		RO3	
	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €
HTF	0.00	0.00	0.00	0.00	2 074	140.00
Plasticiser Aviation	750	50.63	1 500	101.25	1 500	101.25
Plasticiser non-Aviation and Other Uses	24	1.62	24	1.62	24	1.62
Total per RO	**774**	**52.25**	**1 524**	**102.87**	**3 598**	**242.87**

Eastman Chemical has announced to invest up to 1 billion US$ in a material-to-material molecular recycling facility in France to recycle up to 160 000 tonnes annually of hard-to-recycle plastic waste that is currently being incinerated. The plant and an innovation centre would be expected to be operational by 2025, creating employment for approximately 350 people and leading to an additional 1 500 indirect jobs in infrastructure and energy. The most suitable and efficient technology would be based on Terphenyl, hydrogenated as HTF. The

[103] https://echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d
[104] The average gross salary was estimated based on an average EU gross earning of € 13.7/h uplifted to 2020 (Eurostat), 40.3 hours work weeks (Eurostat, 2018b) and 33 holidays per year (European Data Portal, 2016).
[105] af3a487e-65e5-49bb-84a3-2c1bcbc35d25 (europa.eu)
[106] https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf

economic impacts of this project have not been evaluated and included in the calculation but could add additional costs to RO3 if technology based on Terphenyl, hydrogenated would not be available.

E.6.2. Wider economic impacts

The proposed restriction (RO1) is not expected to affect competition between EU and non-EU actors placing products on the market in the EU significantly, due to the derogation for the use of Terphenyl, hydrogenated in HTF applications and the time-limited derogation for plasticiser uses in the aviation industry. It is expected that after 5 years of derogation, the aviation plasticiser industry will have successfully substituted Terphenyl, hydrogenated in this application.

In contrast, implementation of RO3 would create distortion and unfair competition, since many products (e.g., PET) could be produced outside the EU using the more competitive heat transfer systems based on the use of Terphenyl, hydrogenated. Moreover, in case of a complete Terphenyl, hydrogenated ban, some chemicals could not be produced in the EU anymore, which would play against the objective of a sustainable and self-sufficient EU chemical industry. In addition, Terphenyl, hydrogenated is used in certain key renewable energy technologies, therefore any ban would undermine the EU Green Deal activities related to clean energy production to address climate change. Due to the lack of information, those potential economic impacts have not been quantified.

E.6.3. Distributional impacts

The distributional impacts are not societal costs as such, as a negative impact on one actor can be counterbalanced by an equal but positive impact on another actor. However, distributional impacts may still be important, in particular, if "losing" actors are part of a vulnerable group.

Information received in the stakeholder consultations indicates that the main sectors adversely affected by a restriction on Terphenyl, hydrogenated are the general manufacture of chemicals (including PET production), energy generation (via ORC systems), and the aviation industry. These cover large sectors with a strong presence in the EU, as well as SMEs. Under a full ban of Terphenyl, hydrogenated for all uses (RO3), the potential higher resilience of larger companies to adapt to changes compared to smaller businesses would not play a role; since it is not expected that feasible alternatives to Terphenyl, hydrogenated in its use as HTF (that would not lead to regrettable substitution in the future) will be available to downstream users in the short term, all industries (large or small) would be expected to be impacted in a similar way. Distribution of profits to industries that would transition early to different substances in the HTF sector does not play a role in the evaluation and therefore incentives for a proactive transitioning away from an SVHC cannot be considered.

E.7. Practicality and monitorability

E.7.1. Implementability and manageability

Implementability is related to the degree in which the actors involved are capable to comply with the restriction proposal. On the assumption that no feasible alternatives for Terphenyl, hydrogenated are available for the use as HTF, without generating a situation of regrettable substitution, it is evident that RO3, leading to a full ban of Terphenyl, hydrogenated, would be complex to implement and manage for many users of Terphenyl, hydrogenated. Companies would be forced to change their production processes to either using other products that would likely result in similar regulatory action in the future, or a complete redesign of the heat transfer systems, which would lead to significant costs; relocation or closure of activity would be the other alternative options. In contrast, RO1 would allow continued use of Terphenyl, hydrogenated in the main application, provided that the relevant actors would adapt their installations to specific technical requirements. RO1 would also allow for sufficient time for the aviation industry to switch to alternative products in the use of Terphenyl, hydrogenated as a plasticiser in this sector. To be implementable within a reasonable timeframe, a restriction should be designed that a supervision mechanism exists and is practically implementable for enforcement authorities. The proposed restriction (RO1) is easily understandable for effected parties and therefore implementable and manageable. Furthermore, it is implementable as companies can test for concentration limits in concerned articles or make it a condition of sourcing contracts. In addition, the proposed restriction provides sufficient time to the impacted supply chains to transition.

E.7.2. Enforcement and monitorability

To be enforceable, a restriction needs to have a clear scope so that it is obvious to enforcement authorities which products are within the scope of the restriction and which are not. Moreover, the restriction needs a concentration limit value that can be subject to supervision mechanism. The proposed RO1 provides these prerequisites. The monitoring of the proposed restriction is expected to be done through enforcement.

Enforcement activities under RO1 should focus on two actions; firstly, authorities should verify that downstream users of Terphenyl, hydrogenated as a HTF adapt their installations - if needed - to introduce appropriate means of containment to minimise releases and ensure adequate collection of any potential release of the substance. This could be developed via identification of the relevant actors using Terphenyl, hydrogenated in this sector and implementation of inspections by the relevant Member States.

The second action would be related to the import of Terphenyl, hydrogenated into the EU, as such, in mixtures or in articles, and the production of articles in the EU. For articles placed on the market, authorities could check the documentation from the supply chain confirming that articles do not contain Terphenyl, hydrogenated. The SCIP Database could be useful to identify, if new articles have been notified after the restriction, that do contain Terphenyl, hydrogenated in order to identify non-compliance. In addition, it is expected that the verifications will be carried out via testing. A concentration of 0.1% w/w is the limit that is applicable to Terphenyl, hydrogenated in articles, as this is the limit that triggers notification requirement under article 7(2) of REACH, and the information requirement under REACH Article 33.

The concentration limit of 0.1% w/w would therefore provide an option to establish enforceability criteria for articles containing Terphenyl, hydrogenated. However, this limit would be also applicable to Terphenyl, hydrogenated as a substance and in mixtures.

Terphenyl, hydrogenated as a pure substance (100% concentration) meets the criteria for classification as hazardous in accordance with CLP Regulation because it is classified by co-registrants as Aquatic Chronic 2 (H411: Toxic to aquatic life with long lasting effects). For this reason, and according to Article 31 of the REACH Regulation, its SDS must be available and the suppliers shall provide it to the customers.

This classification must be considered when Terphenyl, hydrogenated is placed in the market as a mixture. As the substance has not a defined M factor (default value of 1) and according to Part 4 of Annex I to CLP Regulation, any mixture containing Terphenyl, hydrogenated will be classified due to environmental hazards if the concentration of Terphenyl, hydrogenated is ≥ 2.5% w/w. However, according to Article 31 of the REACH Regulation, any mixture containing a vPvB substance in a concentration ≥ 0.1% w/w must be its SDS available, even if the mixture does not meet the criteria for classification as hazardous in accordance with CLP

Regulation. Therefore, the suppliers of any mixture containing Terphenyl, hydrogenated in a concentration ≥ 0.1% w/w must be the SDS available and it shall be provided to the customers at their request.

In conclusion, the concentration of 0.1% w/w can be considered the concentration limit for Terphenyl, hydrogenated as a substance and in mixtures, because it triggers the information requirement under REACH Article 31.

Analytical methods for quantitative determination of Terphenyl, hydrogenated are available via NIOSH 5021 "o-Terphenyl" NIOSH Manual of Analytical Methods (NMAM), Fourth Edition. This method could be used for the purpose of establishing concentrations of Terphenyl, hydrogenated in articles, however its implementation may require certain adaptations by specialised laboratories. The method is available in the public domain[107].

The NIOSH 5021 analytical method for the determination (identification and quantification) of o-terphenyl has been applied to air samples (PTFE filters for the sampling of inhalable dust) and soil samples (bulk). The methodology used for the collection of these samples is described in **Annex B.9.3.3**. The reporting limits are 0.4 µg for air samples and 1.0 µg for soil samples.

No determination of o-terphenyl in liquid samples was performed during the exposure measurements, although the method used in the analysis of liquid samples would be the same.

This is the only available method for the determination of o-terphenyl and it is also used for the quantification of m-Terphenyl, p-terphenyl, and other hydrogenated terphenyls (CDC, 2019), although the results are always expressed as o-terphenyl.

This indirect method can be used for enforcement because, according to the available bibliography to the DS, o-terphenyl is not component of other substances than Terphenyl, hydrogenated. The US National Library of Medicine states that o-terphenyl is usually shipped as a mixture with its isomers m-terphenyl and p-terphenyl that is commonly used as a heat transfer fluid, being this the definition of Terphenyl, hydrogenated[108].

O-terphenyl (CAS 84-15-1) is not a chemical product itself and it is not marketed as an individual substance globally. Furthermore, it has not been registered under REACH. In the ECHA website o-terphenyl can be found alone or included in other reaction mass substances. Only one of these reaction masses has been registered (EC 904-797-4). This means that the other substances cannot be commercially available in the EU and, therefore, they cannot be used in any European site and no detection of o-terphenyl should be expected from them.

Regarding the only registered substance, it is a reaction mass of o-terphenyl and m-terphenyl, that might contain p-terphenyl as impurity. The substance is only imported in a volume lower than 100 tonnes per year, very far of the volumes marketed for PHT (1 000 to 10 000 tonnes). Therefore, any interference between both substances during the determination of o-terphenyl (e.g., during enforcement) can be considered highly unlikely.

Due to the classification of Terphenyl, hydrogenated as vPvB, notification of any violation of the restriction in the RAPEX System[109] is not relevant, since it only applies to dangerous products, not vPvBs.

E.8. Proportionality (comparison of ROs)

Proportionality is a general principle of EU law. It restricts authorities in the exercise of their powers by requiring them to strike a balance between the means used and the intended aim. More specifically, proportionality requires that advantages due to limiting the right are not outweighed by the disadvantages to exercise the right. In other words, the limitation on the

[107] 5021.new (cdc.gov)
[108] https://pubchem.ncbi.nlm.nih.gov/compound/O-Terphenyl
[109] Safety Gate for dangerous non-food products (europa.eu)

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right must be justified. A pre-condition is that the measure is adequate to achieve the envisaged objective. As highlighted in Section E.5, the risks and thereby the benefits of PBT and vPvB substances cannot be quantified, and in the case of vPvBs, there are no known impacts. This prohibits the use of a traditional cost-benefit analysis to assess proportionality. To evaluate the acceptability of regulatory options despite the lack of quantitative information on benefits, SEAC recommends using C/E values and "a comparator or a "benchmark" on the level of costs that are deemed to be worthwhile taking when reducing emissions" (ECHA, 2014). The total cost of introducing a restriction on Terphenyl, hydrogenated is higher for the more stringent ROs (RO2 and RO3) and the largest cost component by far is the potentially loss of profits due to not having a feasible alternative to switch to in case of a full ban (RO3), mainly related to the use of the substance as HTF. Equally, the more stringent restriction scenario, would lead to the higher emission reductions and, by proxy, higher potential environmental benefits. The main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of Terphenyl, hydrogenated vs. the cost to industry and society from potential investment costs and profit and job losses, as well as to supply disruption for products that may be difficult to produce without access to Terphenyl, hydrogenated as a HTF (e.g., PET). Based on the lack of feasible alternatives, it is difficult to evaluate substitution costs and R&D activities in detail.

Table 87 provides a comparison of environmental emissions versus expected costs, jobs at risk and the social impacts for the different ROs evaluated.

Table 87. Total economic impacts vs Emission values and Emission Reduction Capacity

	Total Cost (in Million €)	**Social Impacts** (in Million €)	**Total Economic Impact** (in Million €)	**Total Emissions** (tonnes)	**Emissions Reduction Capacity** (%)
Baseline				19 584	0
RO1	118.96	52.25	171.21	3 006	85
RO2	201.82	102.87	304.96	686	96.5
RO3	10 656.24	242.87	10 899.11	0	100

To determine whether the estimated costs of kg/PBT substance emissions reduced are likely acceptable for EU society, SEAC recommends using a benchmark to compare the cost against. There are currently no agreed benchmarks for PBT and vPvB substances, but a comparison could be drawn based on previous studies and estimated costs of regulations implemented in the past, e.g., Oosterhuis and Brouwer (IVM, 2015). The conclusion drawn in the paper is that costs below 1,000 € per kg reduced emission is generally deemed acceptable.

Table 88 shows the C/E estimates for each RO. The proposed RO1 has a high cost-efficiency (10€/kg Terphenyl, hydrogenated emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1.

Table 88. C/E of all ROs

	Total Economic Impact (€)	Total Emissions (tonnes)	Total Emissions (kg)	Terphenyl, hydrogenated Reduced against Baseline (kg)	C/E (€/kg Terphenyl, hydrogenated)
Baseline		19 584	19 584 000	-	-
RO1	171 205 000	3 006	3 006 000	16 578 000	**10**

RO2	304 690 000	686	686 000	18 898 000	**16**
RO3	10 899 105 000	0	0	19 584 000	**557**

The cost-efficiency falls within the benchmark zone for being acceptable.

RO2 has with 96.5% a higher emission reduction capacity but a lower C/E with a factor of 1.6 (16€/kg Terphenyl, hydrogenated emissions avoided) compared to RO1. RO3 as most stringent RO has the highest emission reduction potential but at much higher costs (557€/kg Terphenyl, hydrogenated emissions avoided), which are a factor of ca. 58 compared to RO1.

Please note that the high and low volume emission scenarios were averaged to an estimated Terphenyl, hydrogenated release of 925 tonnes in 2021, potentially a slight overestimate. The DS agrees that it is debatable, if an 85% emission reduction for a vPvB substance is sufficient. 5 years after Entry into Force of the Restriction (e.g., 2030), the plasticiser use in aviation will cease, which will limit the emissions to the HTF use, which is marginal.

The proposed RO1 has a high C/E coupled with an acceptable emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1 in order to respect the proportionality principle.

The main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of Terphenyl, hydrogenated vs. the cost to industry and society from potential investment costs and profit and job losses, as well as to supply disruption for products that may be difficult to produce without access to Terphenyl, hydrogenated.

Comparing with other PBT/vPvB substances under restriction, C/E values of 464 €/kg for DecaBDE[110] and 20 000 €/kg for DP were developed. In the Microplastics Restriction Report[111], ECHA developed for leave-on cosmetic products a cost-efficiency of 430 €/kg of reduced emissions. **Table 89** shows C/E ratios of other recent REACH restriction.

Table 89. C/E-Ratios of recent (incl. ongoing) REACH Restrictions

REACH Restriction	**€/kg**
Lead Gunshot in Wetlands	9
PAHs in Clay Targets	130
Lead in PVC	308
D4/D5 in Wash-off Cosmetics	415
DecaBDE	464
Phenylmercury Compounds	649
PFOA Substances	734

E.9. Conclusion

To identify the most appropriate measure to address the risks of the Terphenyl, hydrogenated use, an analysis of risk management options (RMOA) was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs, and it was concluded that a Restriction under REACH is the most appropriate risk management option.

A number of ROs were assessed on the basis of effectiveness, practicality, and proportionality. The conclusion of the Dossier Submitter's assessment is to **propose Restriction Option 1**.

[110] Registry of restriction intentions until outcome - ECHA (europa.eu)
[111] Registry of restriction intentions until outcome - ECHA (europa.eu)

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The proposed restriction is targeted to the exposure that are of most concern, e.g., the use of Terphenyl, hydrogenated as a plasticiser. The proposed restriction is effective and reduces potential risks to an acceptable level within a reasonable period of time. It is assumed to impose low costs to reduce a potential risk and that the measures are proportionate to the risk. The restriction is practical because it is implementable, enforceable, and manageable, as the proposed restriction is easy to understand and communicate down the supply chain. Testing and sampling methods exist for enforcement activities.

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Annex F: Assumptions, uncertainties, and sensitivities

This Annex sets out the key variables and assumptions used in the analysis (Section F.1. Input parameters and assumptions) and identifies uncertainties induced by uncertainty in the input parameters used (Section F.2. Uncertainty).

F.1. Input parameters and assumptions

A large number of input parameters and assumptions have been used to derive the quantitative results in the restriction proposal. All input parameters and assumptions are reported throughout the report. Therefore, the Dossier Submitter does not see the necessity to repeat in particular the input factors in this section.

The input parameters on **Volumes & Uses** (**Annex A**) as well as number of sites using Terphenyl, hydrogenated are considered to be quite accurate, since consistent data was provided from industry during the stakeholder consultations and direct interviews with concerned parties.

Related to the input parameters on the **Exposure Assessment** (**Annex B.9.**), all assumptions have been referenced in the respective tables. Exposure values have been derived by applying defaults according to ECHA Guidance R.16. For the plasticiser uses a FEICA SpERC (FEICA SPERC 5.1a.v3) was applied for the refinement of the default assumptions. The estimates of the refined assessment are referred to as "lower estimate". They are assumed to represent the reasonable worst-case emissions. The high emission scenario represents a worst-case assumption whereby e.g., the default release factors as indicated in ECHA Guidance R.16 are used. Hence, the high emission scenario has to be regarded as a very conservative approach overestimating real exposure levels. Regarding the migration modelling, it needs to be noted that this is an abstract process aiming at calculating the maximum number of substances which might be transferred to the medium in contact, with various simplifications and assumptions. It is important to understand that the migration modelling used for the purpose of this proposal does not seek to reproduce all the details of the real mechanisms; instead, the objective is to provide an estimate of potential migration for getting an indication of potential emissions into the environment via the migration path of plasticizers used in coatings, sealants, and articles. The Dossier Submitter assumes that some additional Terphenyl, hydrogenated volume will be entering the EU via articles, due to the high number of notifications in SCIP. It is to be noticed that the number of articles containing Terphenyl, hydrogenated imported into the EU and exported from the EU is not known with any certainty. Hence, the exposure assessment for the service life scenarios is based on the volume of Terphenyl, hydrogenated itself supplied to the EU market.

Please note that the SCIP Database was referenced as an additional data source for estimating volumes and trends in conjunction with the Baseline Emissions. The Baseline describes the expected trends that would occur without the introduction of any new regulatory measure. Therefore, a restriction on Terphenyl, hydrogenated is not included in this trend scenario.

Concerning the **Baseline** scenario (**Annex D**), the Dossier Submitter assumes an average growth trend for the HTF use of 5% annually and a stagnant trend for the plasticiser applications from 2025-2035. Beyond 2035, the uncertainty in any projection increases and makes it difficult to identify the driving factors for the plasticiser use. The Dossier Submitter assumes that due the SVHC listing the reformulation will kick in for applications where substitution can be achieved easily, resulting in a drop of the plasticiser use in the EU. The identification of a substance as a SVHC and its inclusion in the Candidate List triggers certain legal obligations for the importers, producers and suppliers of mixtures and articles that contain such a substance, which results in higher efforts to market the substance. In addition, SVHC substances are in general blacklisted by NGO or included in industry sector specific declaration or ban lists. It is expected that the decrease in volume as of 2036 will be 5% per annum. On the other hand, it is very likely that the production of articles including Terphenyl,

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hydrogenated as a plasticiser will be relocated outside the EU and that the volume of imported articles containing Terphenyl, hydrogenated into EU will increase.

The **Impact Assessment** (**Annex E**) of this dossier is surrounded by various assumptions and uncertainties. The behavioural responses are based on comments made by industry via the stakeholder consultations. The same applies for the Economic Impacts as outlined in **Annex E.4.** and **Annex E.6**. Most of the input data was derived from responses of industry. It should be noted, that due to the similarity of the application of Terphenyl, hydrogenated in the aviation industry compared with the use of DP in Aviation, the same approach and figures developed in the DP restriction was used. Regarding loss in efficiency when using an alternative substance for the HTF use, an amount of 25 000 € per installation was used. There is a lot of uncertainty if this number is matching reality.

Related to the Risk Reduction Capacity (E.5.) the model assumes that emissions cease when the use of Terphenyl, hydrogenated is banned for a certain use. In reality, parts of the emissions particularly for the use as plasticiser will occur during the service life of the articles including Terphenyl, hydrogenated and thus, after the ban is in force. A significant share of the emissions occurs at the end-of-life stage. Furthermore, if the use as HTF is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (about 25 000 tonnes in about 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis.

Assumptions made, in particular in the cost assessment, should be tested and verified in the stakeholder consultation on this Annex XV dossier.

F.2 Uncertainty

Exposure assessment

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R.16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach has been chosen in line with ECHA Guidance R.16.

The lack of information on fractions released to air, water, and soil from the various processes during Terphenyl, hydrogenated's lifecycle creates significant uncertainties in the exposure assessment.

The approach used is based on a combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SpERCs) and default release factors from ECHA Guidance R.16. In 2018 an Exposure & Release Questionnaire was sent out to users of Terphenyl, hydrogenated. Information obtained from this questionnaire is also used in the exposure assessment. It is uncertain though whether the used information is applicable to all sites where Terphenyl, hydrogenated is used in the same way.

The share of the total emissions was evaluated based on the market sector. The analysis showed that the HTF use has by far the largest share of the total emission in the high emission scenario. All other uses have a share of a few percent, each. However, the result of the high emission scenario is not regarded as reliable since the actual emission associated with the industrial use of Terphenyl, hydrogenated is unrealistic and overestimates the actual emission. For further information please refer to Section B.9.3.1.

Consequently, the high share of the total of the high emission scenario and the share of the individual use needs to be interpreted with caution.

Looking at the low emission scenario the "Service life of articles produced from use as plasticiser" has a share of approximately approx. 32 % of the total emissions followed by the

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“Direct use for industrial coatings/inks applications” (approx. 24 %) and “Service life of articles produced from use of coatings and inks” (approx. 17 %).

A differentiation between plasticizer (non-aviation) and plasticizers for use in aviation was not made and the expected releases are just based on the volumes used in these sectors.

For certain input factors assumptions had to be made based on best knowledge. This is also associated with a higher uncertainty. Moreover, for the fraction released to solid waste for some of the uses no information is available. Hence the emissions are possibly underestimated for those uses. Furthermore, treatment of waste as well as treatment of articles at the end of their service lifetime is not certain.

Details of the specific factors used are given for each individual use in Section B.9.

The Predicted Environmental Concentrations (PECs) have been estimated using EUSES v2.1.2 as implemented in CHESAR v3.7. This model uses basic information on the properties of Terphenyl, hydrogenated and, combined with estimates of the amounts of Terphenyl, hydrogenated released, calculates the resulting concentrations in the environment using standard models.

The approach used is generic and uncertainties arise in modelled outputs from a number of sources as well. It is to be noticed that the number of articles containing Terphenyl, hydrogenated imported into the EU and exported from the EU is not known with any certainty. In addition, it is an uncertainty if a restriction of imported articles with Terphenyl, hydrogenated content of greater than 0.1% w/w is considered sufficient to adequately address the concerns or if the restriction should cover concentrations as well < 0.1%, since REACH Article 7(2) on “Notification Requirements”, Article 33 on “Supply Chain Communication” and the “SCIP Notifications” do not apply. This is an uncertainty since it is not clear, how many articles with concentration levels < 0.1% of Terphenyl, hydrogenated are being imported and if those imported articles would pose a risk of environmental exposure.

Exposure measurements

Related to the exposure measurements, attempts were made to capture releases of Terphenyl, hydrogenated from industrial sites operating high temperature, non-pressurized heat transfer systems using the substance as a HTF. Air samples were collected from locations from which it was assumed that Terphenyl, hydrogenated was more likely to be released. However, no significant concentrations of Terphenyl, hydrogenated were detected from the samples that were generated. This can be due to many factors, since the set-up largely depended on capturing situations from which Terphenyl, hydrogenated would be released in a state that could be captured by a nearby air sample collector. This proved to be difficult for many reasons, one of them being the limited time duration of the sampling (approximately four hours per sample). Furthermore, the low volatility of Terphenyl, hydrogenated makes it difficult for the substance to be released a measurable way in a non-continuous sampling system. In contrast, additional information obtained during the monitoring exercise has shown to be valuable in terms of identifying potential releases of Terphenyl, hydrogenated. While limited in number, the soil samples that were collected at one site resulted in detection of Terphenyl, hydrogenated (or its compounds identifiable via analytical techniques). In addition, an event occurred in which releases of Terphenyl, hydrogenated from a HTF were visually observed during the sampling. These events suggest that while limited, Terphenyl, hydrogenated releases at industrial establishments are possible and may accumulate over years of operation, particularly if systems are not operated under strictly controlled containment systems.

Cost and C/E

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The estimated costs for the ROs are associated with some degree of uncertainty. Information received from individual actors during the stakeholder consultation were extrapolated to entire industries. This poses uncertainty, as the exact data for non-responding companies are unknown. Moreover, the accuracy of the collected data and the robustness of the adopted methodology introduce uncertainty. This methodology has been described in detail in **Annex E.4.** (Economic Impacts). In particular, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling sites, may be subject to uncertainty. Assumptions made on behavioural responses are intrinsically uncertain.

The C/E calculations incorporate both, emissions, and costs, thus, the same uncertainties described before will apply to the C/E-estimates as well. It is hardly possible to reduce these uncertainties any further without more information from stakeholders. Therefore, the conclusions of this dossier should be verified in the stakeholder consultation of this Annex XV dossier.

F.3. Sensitivity analysis

Adopting only the most likely value (estimated or average) of each impact within an Impact Analysis provides no indication of the level of uncertainty surrounding the analysis and hence has implications for any decisions based on the conclusions. Instead, it is recommended that information be developed on the range of plausible outcomes associated with a given option. This type of information is developed through the use of sensitivity analysis, which is a generic term for the techniques that involve identifying key assumptions (or variables) for which uncertainty as to their values could significantly affect the conclusions drawn on costs or benefits. Sensitivity analysis is therefore used to identify the variables that contribute most to uncertainty in predictions.

As highlighted in Section F.2., there are uncertainties associated with some of the input factors and consequently results of the analysis. However, since the use volumes have been identified as reliable and the exposure assessment was conducted according to ECHA Guidance, the dossier is considered to be robust.

The key uncertainties are considered to be the quantitative data on emissions and release estimates versus those associated with exposure estimates in HTF uses, profit losses, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling of sites. Due to the high uncertainty of the quantitative release estimations, a qualitative assessment was conducted. In addition, strictly controlled closed systems and associated RMMs and OCs were defined. Moreover, another key uncertainty is related to the plasticisers uses in aviation and non-aviation related to availability of alternatives as well as uses of Terphenyl, hydrogenated in non-plasticiser applications, since no feedback could be obtained during stakeholder consultations. Furthermore, treatment of waste as well as treatment of articles at the end of their service lifetime is not certain.

Table 90 shows in a simple manner the sensitivity of key outcomes of the Impact Analysis. The arrows indicate the impact of the uncertainty of some key parameters on the outcomes of the SEA. "↓" means, that the assumption lowers the estimate and"↑" means that the assumption increases the estimate.

Table 90. Sensitivity of key uncertainties

Parameter tested	**Impact on Emissions**	**Impact on Costs**	**Impact on C-/E-Ratio**
Quantitative data on HTF emissions underestimated	↑	None	↓

Non-availability of alternatives for plasticiser and non-plasticiser applications	↓	↑	↑
EoL management of articles	↓↑	Unknown	↓↑
Market growth rate underestimated	↑	None	↑
Market growth rate overestimated	↓	None	↓
Cost overestimation	None	↓	↓
Cost underestimation	None	↑	↑

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Annex G: Stakeholder information

Extensive information is available on Terphenyl, hydrogenated related to its use patterns. The REACH Registration Dossier (ECHA, 2021a), the CSR document (Solutia, 2019), the Annex XV Dossier (Tukes, 2018) and the information available from the ECHA Website on Terphenyl, hydrogenated (ECHA, 2021f) were used as important sources for information. In order to complement these sources, detailed stakeholder interactions took place during the Public Consultations in the SVHC identification process and the ECHA Prioritization Process, which did include the call for information on Socio Economic Impacts by the COM.

On 5 March 2020 until the 5 of June 2020, the ECHA, on behalf of the COM, launched a call for information in order to obtain data on the uses and conditions of use of substances considered in the Draft 10th recommendation for prioritisation of substances for inclusion into Annex XIV. In the framework of this call, the COM asked for submission of information on the possible economic, social, health and environmental impacts (costs and benefits) of possible inclusion into Annex XIV. The questionnaire template is included in the Restriction Proposal (see template in Appendix 3). A summary of the inputs to the call for information on socio-economic elements related to ECHA's 10th draft Recommendation for prioritisation was presented by the COM on the 40th Meeting of Competent Authorities for REACH and CLP (CARACAL)[112] on the 29th of June 2021. The Annex to the COM Summary[113] included 26 non-confidential documents submitted by industry as shown in **Table 91** below.

50% of the comments received by the COM were related to Terphenyl, hydrogenated, the remaining 50% were allocated to the other 6 substances that were included in ECHA'S recommendation. This is reflected by the feedback to ECHA, where the responses on ECHA's Draft 10th Recommendation for Terphenyl, hydrogenated [114] include 57 pages, and > 50% of all responses related to the recommended 7 substances where related to Terphenyl, hydrogenated.

Table 91. Stakeholders responding to the call for Socio-Economic information by the COM

Terphenyl, hydrogenated	Chemical, Pharmaceutical, PET, Metal and Aerospace	IPI Global
		Framatome
		Indorama (NL)
		Adven
		JSC Neo GROUP
		Sipol
		Uniconfort
		Palsgaard
		660 Individual France
		STEAG new energies
		ADM SIO
		Grupa Azoty
		Leroux
		677 Individual Germany
		678 Individual Germany
		DSM
		Hydro Aluminium
		Indorama Spain
		ASD
		GIFAS
		Germany MS
		AR Metallizing
		WKO
		BASF
		AIA
		Rodun

112 Circabc (europa.eu)
113 Circabc (europa.eu)
114 Submitted recommendations - ECHA (europa.eu)

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Furthermore, the Dossier Submitter had several telephone interviews with the Lead- and Member Registrants as well as individual users of the substance via its consultant.

In early 2018, the LR of Terphenyl, hydrogenated conducted a simplified socio-economic impact analysis for Terphenyl, hydrogenated, in the context of the process to identify Terphenyl, hydrogenated as SVHC. It was based on responses to a questionnaire (see template in Appendix 2) addressed to their downstream users. 24 completed questionnaires were received from SMEs and large companies, including HTF uses in different industrial sectors (aluminium, polymers, chemicals, ORC) and plasticiser users (sealants, coatings, adhesives). This information was used for the preparation of the Risk Management Option Analysis of the Dossier Submitter in 2020 (ISS, 2021).

In the course of the restriction proposal preparation, the Dossier Submitter launched, between the 21 of June and the 30 of September 2021, a SEA Questionnaire (see template in Appendix 4) to the Terphenyl, hydrogenated value chain, including manufacturers, importers, downstream users, article manufacturers and equipment manufacturers (e.g., boiler makers) via its technical consultant. In addition, some relevant industry associations were contacted. In total about 250 questionnaires were sent and 29 replies were received from different industry sectors. Further information is available under "**Annex E.4.** Economic Impact".

In conclusion, there were several opportunities for stakeholders to contribute and many responses and contributions were received and evaluated.

Regarding the representativeness of the responses sent by the stakeholders, related to the different uses of Terphenyl, hydrogenated, these are the main results[115]:

Table 92. Number of responses received per use

	LR SEA 2018	COM 2020	DS SEA 2021
Responses received	24	31	29
Responses from DUs	**22**	**27**	**27**
Use as HTF	15	24	27
% Responses HTF	**68**	**87**	**100**
Use as plasticiser	7	3	0
% Responses Plasticiser	**32**	**13**	**0**
Other uses	0	0	0
% Responses Other	**0**	**0**	**0**

On LR SEA 2018 two responses have been received from one manufacturer of Terphenyl, hydrogenated and one equipment/plant design company. On COM 2020 four responses have been received from two distributors, one equipment/plant design company, and one economic association. On DS SEA 2021 two responses have been received from one manufacturer of Terphenyl, hydrogenated and one distributor. These responses have not been considered in this analysis as these respondents are not considered as DUs.

As can be seen, the responses from DUs using Terphenyl, hydrogenated as plasticiser has been decreasing from 2018 (32% of the responses) to 2021 (no responses). A reasonable explanation for this fact could be that the industry involved in this use has already started

[115] Note that the responses to the ECHA Public Consultation (55) were not analysed. However, Annex E of the Restriction Proposal Annex does provide further details

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the reformulation/ substitution process of the substance and, therefore, they are not interested in defending this use of Terphenyl, hydrogenated.

The sectors of use of the respondents (DUs) using Terphenyl, hydrogenated as heat transfer fluid are the following:

Table 93. Number of responses received per sector of use in HTF use

	LR SEA 2018	COM 2020	DS SEA 2021
Petrochemicals and basic chemical production	9	9	22
Plastic and rubber production	1	7	2
Electricity, Gas and Steam Production	4	3	0
Coatings	0	0	1
Food and pharmaceutical	0	3	0
Construction	0	1	2
Industrial processing machinery production	1	0	0
Packaging	0	1	0
Total	**15**	**24**	**27**

The sectors of use of the respondents (DUs) using Terphenyl, hydrogenated as plasticiser are the following:

Table 94. Number of responses received per sector of use in plasticiser use

	LR SEA 2018	COM 2020	DS SEA 2021
Petrochemicals and basic chemical production	1	0	0
Aerospace	1	3	0
Coatings	3	0	0
Packaging	1	0	0
Adhesives and sealants	1	0	0
Total	**7**	**3**	**0**

As can be seen, all the responses received in COM 2020 regarding the use of Terphenyl, hydrogenated as plasticiser came from the aerospace sector. This could mean that this is the only industrial sector that is still interested in this specific use. However, no responses from this sector have been received in the last public consultation (DS SEA 2021).

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REFERENCES

Adams W.J. Aquatic Toxicity of Therminol 66/Santosol 340/HB-40. *Monsanto Industrial Chemicals Company*. Report number: XX-92-9965. **1979**. (summary sheet of experimental data)

Adamson I.Y., and Furlong, J.M. The fate of inhaled and ingested tritiated terphenyls in mice. *Archives of Environmental Health.* 28(3), 155-158. **1974.**

Adamson I.Y., and Weeks JL. The LD50 and Chronic Toxicity of Reactor Terphenyls. *Archives of Environmental Health*. **1973** Aug; 27(2):69-73.

Adamson IYR., Bowden DH., and Wyatt JP. The Acute Toxicity of Reactor Polyphenyls on the Lung. *Archives of Environmental Health*. **1969** Oct; 19(4):499-504.

Baltussen E. Report. Determination of physico-chemical properties of Therminol 66: partition coefficient and adsorption coefficient. *Notox BV*. Report number 494653. **2010**.

BTL 1972. Report. Results of four-day static fish toxicity studies in Rainbow trout and bluegills. *Industrial Bio-Test Laboratories, Inc*. Report number: BTL 72-83. **1972**.

Calvert et al. Report. Acute Toxicity of XA2020 to Chironomus Tentans. *Monsanto Industrial Chemicals Company*. Report number: ES-82-SS-76. **1982**.

CDC 2019. NIOSH Pocket Guide to Chemical Hazards for o-terphenyl (https://www.cdc.gov/niosh/npg/npgd0591.html), m-terphenyl (https://www.cdc.gov/niosh/npg/npgd0592.html), and p-terphenyl (https://www.cdc.gov/niosh/npg/npgd0593.html). *The National Institute for Occupational Safety and Health (NIOSH). Centers for Disease Control and Prevention (CDC)*. October **2019**.

CDC 1994. NIOSH method 5021. o-Terphenyl. https://www.cdc.gov/niosh/docs/2003-154/pdfs/5021.pdf NIOSH Manual of Analytical Methods (NMAM) 4th Edition. *The National Institute for Occupational Safety and Health (NIOSH). Centers for Disease Control and Prevention (CDC).* **1994**.

CEN 1995. EN 481:1995 Workplace atmospheres. Size fraction definitions for measurement of airborne particles. *European Committee for Standardization*. **1995**.

Clark CR., Marshall TC., Merickel BS., Sanchez A., Brownstein DG., and Hobbs CH. Toxicological assessment of heat transfer fluids proposed for use in solar energy applications. *Toxicology and Applied Pharmacology*. **1979**; 51(3): 529-35

Cui J and Forssberg E. Mechanical recycling of waste electric and electronic equipment: a review. *Journal of Hazardous Materials B99*. **2003**; 243–263.

Damiani MR. Radco Industries Inc. Selecting Heat Transfer Fluids: Synthetic or Hot Oil? *Process Heating*. October 1, **1998**.

Danish EPA 2014. Survey of biphenyl. Part of the LOUS review. Public consultation version. *Miljøstyrelsen - The Danish Environmental Protection Agency*. November **2014**.

DERWIN 2012. DERWIN v2.02. U.S. Environmental Protection Agency. **2012**.

Dow 2017. Safety data sheet for DOWTHERM™ RP. English version 9.1. Revision Date: 23.05.2017. https://www.dow.com/es-es/document-viewer.html?docType=SDS&contentType=SDS&product=51244z&tradeProduct=0000

00051244&selectedCountry=GB&selectedLanguage=EN&recordNumber=27342742 *Dow Chemical Company Limited*. **2017**.

Eastman 2022a. Process fluids selection guide. https://www.eastman.com/Literature_Center/M/MCS3500.pdf *Eastman Chemical Company*. Last access March **2022**.

Eastman 2022b. Technical Data Sheet Biphenyl. https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71093414&pn=Biphenyl#_ga=2.10285941.1130342050.1656706865-1352314490.1656706865 *Eastman Chemical Company*. Last access July **2022**.

Eastman 2022c. Technical Data Sheet Therminol® 66 Heat Transfer Fluid. https://productcatalog.eastman.com/tds/ProdDatasheet.aspx?product=71093438&pn=Therminol+66+Heat+Transfer+Fluid#_ga=2.77543381.1130342050.1656706865-1352314490.1656706865 *Eastman Chemical Company*. Last access July **2022**.

ECHA 2022a. CHESAR. CHEmical Safety Assessment and Reporting tool. https://chesar.echa.europa.eu/es/home *European Chemicals Agency*. Version used: 3.7.

ECHA 2022b. EUSES. European Union System for the Evaluation of Substances. https://echa.europa.eu/support/dossier-submission-tools/euses *European Chemicals Agency*. Version used: 2.1.2. **2022.**

ECHA 2021a. Registration dossier of Terphenyl, hydrogenated (information disseminated in the ECHA website). https://echa.europa.eu/es/registration-dossier/-/registered-dossier/15941 *European Chemicals Agency*. Last access October **2021**.

ECHA 2021b. SCIP Database. https://echa.europa.eu/es/scip-database *European Chemicals Agency*. Last access October **2021**.

ECHA 2021c. C&L Inventory notifications for Terphenyl, hydrogenated. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/79581 *European Chemicals Agency*. Last access September **2021**.

ECHA 2021d. Annex XV Restriction Report for Dechlorane Plus. https://echa.europa.eu/documents/10162/e226337f-0f0d-de37-b1bc-0687817f2615 *European Chemicals Agency.* **2021.**

ECHA 2021e. ECHA webpage. https://echa.europa.eu/home *European Chemicals Agency*. Last access October **2021**.

ECHA 2021f. Substance Infocard for Terphenyl, hydrogenated. https://echa.europa.eu/substance-information/-/substanceinfo/100.057.225 *European Chemicals Agency*. Last access October **2021**.

ECHA 2021g. Assessment of Regulatory Needs. Group Name: Isophthalates, Terephthalates and Trimelliates. https://echa.europa.eu/documents/10162/d4d52e3a-578d-0944-d1c3-e3b489a7e82c *European Chemicals Agency*. Last access December **2022**.

ECHA 2019. Opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6).

DRAFT

https://echa.europa.eu/documents/10162/a3e8195a-23d3-5859-6fdc-7805a3148b46 *European Chemicals Agency*. **2019**.

ECHA 2018a. Support document for identification of Terphenyl, Hydrogenated as a Substance of Very High Concern because of its vPvB properties. https://echa.europa.eu/documents/10162/fb7a9167-7d65-dd4c-2aa2-b8182d4a8e37 *European Chemicals Agency*. **2018**.

ECHA 2018b. Comments on an Annex XV dossier for identification of Terphenyl, Hydrogenated as a Substance of Very High Concern and responses to these comments. https://echa.europa.eu/documents/10162/3cc1642a-cc6d-bc0a-db1b-4d77db6cbd17 *European Chemicals Agency*. **2018**.

ECHA 2017. Guidance on information requirements and chemical safety assessment Chapter R.11: PBT/vPvB assessment. Version 3.0. *European Chemicals Agency*. June **2017**.

ECHA 2017. Guidance on information requirements and chemical safety assessment Chapter R.7c: Endpoint specific guidance. Version 3.0. *European Chemicals Agency*. June **2017**.

ECHA 2016. Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental exposure assessment. Version 3.0. *European Chemicals Agency.* February **2016**.

ECHA 2015. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description. Version 3.0. *European Chemicals Agency.* December **2015**.

ECHA 2014. Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC. https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3 *European Chemicals Agency.* **2014**.

ECHA 2012. Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2.1. https://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258?t=1353935239897 *European Chemicals Agency.* November **2012**.

ECHA 2008. Guidance on Socio-Economic Analysis – Restrictions. https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d *European Chemicals Agency.* **2008**

European Commission 2021a. Proposal for a Restrictions Roadmap under the Chemical Strategy for Sustainability (Draft). https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/15f4818a-982d-4c21-a4e5-a35c9cfec8db/details *DG Environment, Circular Economy, and Green Growth. European Commission*. Brussels, 03/11/**2021**. Doc.CA/51/2021.

European Commission 2021b. Some phthalates and their applications. https://ec.europa.eu/health/scientific_committees/opinions_layman/en/phthalates-school-supplies/figtableboxes/table-2.htm *DG Health and Consumer Protection. European Commission*. Last access October **2021**.

European Commission 2020. EU circular economy action plan. https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en *European Commission*. March **2020**.

FABES 2021. Estimation of Leaching/Migration of hydrogenated Terphenyl. Unpublished reports 7945-21, 7946-21, and 8053-21. *FABES Forschungs-GmbH*. **2021**

Forbis A. Report. Acute Toxicity of Therminol 66 (AB-79-1384354-1c) to Daphnia magna. *ABC Laboratories*. Report number: 23249. **1979**.

Gagel et al. Report. River die away testing of some polyphenyls and some partially hydrogenated polyphenyls. *Monsanto Industrial Chemicals Company. Environmental Sciences Section – NIB*. Report number ES-83-SS-35. **1983**.

Gledhill W. Report. Acute toxicity of Therminol 66 to the mysid (Mysidopsis bahia). *Springborn Bionomics, Inc*. Report number: BP-84-7-57. **1984**.

GMI 2020. Global Cyclohexylbenzene Market Size. https://www.gminsights.com/industry-analysis/global-cyclohexylbenzene-market *Global Market Insights Inc*. December **2020**.

Godek E.G., Naismith R.W., and Matthews R.J. Report. CHO/HGPRT Mammalian cell forward gene mutation assay. Testing facility: Pharmakon Research International, Inc., Waverly, Pennsylvania 18471. Report date: 1985-12-11. Report number: PH 314-MO-005-84. *Study sponsor: Solutia*. Study number: PK-84-150. **1985**.

GR 2020. Hydrogenated Terphenyl. Health-based recommendation on occupational exposure limits. Advisory report. *Gezondheidsraad - The Health Council of the Netherlands*. June **2020**.

Griffin J. Report. Acute Toxicity of Therminol 66 (AB-79-1384353-1b) to Rainbow Trout (Salmo Gairdneri). *Analytical Bio Chemistry Laboratories*. Report number: 23248. **1979**.

HCN 2020. Hydrogenated Terphenyl. Health-based recommendation on occupational exposure limits. No 2020/09. https://www.healthcouncil.nl/documents/advisory-reports/2020/06/15/hydrogenated-terphenyl *Health Council of the Netherlands*. June 15, **2020**.https://www.healthcouncil.nl/documents/advisory-reports/2020/06/15/hydrogenated-terphenyl

Heidolph et al. Report. Bioconcentration of MXP-2020 by bluegill (Lepomis macrochirus). *Monsanto Environmental Sciences Aquatic Laboratory*. Report number ES-83-SS-3. **1983**.

Henderson JS., and Weeks JL.. A study of the carcinogenicity for skin of a polyphenyl coolant. *Industrial Medicine & Surgery*. **1973**; 42(2): 10-21

Hischier R et al. Does WEEE recycling make sense from an environmental perspective? The environmental impacts of the Swiss take-back and recycling systems for waste electrical and. electronic equipment (WEEE). *Environmental Impact Assessment Review.* **2005**; 25: 525 – 539.

Hoberg J. Report. Acute toxicity of Therminol 66 to gammarids (Gammarus fasciatus). *Springborn Bionomics, Inc*. Report number: BW-84-9-1624. **1984**a.

Hoberg J. Report. 48 hours static toxicity test: freshwater invertebrate. *Springborn Bionomics, Inc*. Report number: BW-84-9-1628. **1984**b.

Hollister T. Report. Toxicity of Therminol 66 (BN-79-1384353-ld) to the freshwater alga Selenastrum capricornutum. *EG&G, Bionomics Marine Research Laboratory*. Report number: BP-78-4-65. **1979**.

Hotz K.J., Brewster D. 1990. Report. A Study of Tissue Distribution and Enzyme Induction following administration of Therminol 66 Heat Transfer Fluid to rats. Testing facility: Monsanto Company, Environmental Health Laboratory, 645 S. Newstead Avenue, St. Louis Missouri 63110. Report date: **1990**-07-31. Report number: MSL-10338. *Study sponsor: Solutia*. Study number: ML-87-212.

ISS 2021. Assessment of regulatory needs (RMOA) for Terphenyl, hydrogenated. https://echa.europa.eu/rmoa/-/dislist/details/0b0236e1860ecab8 *Istituto Superiore di Sanità (ISS)*. **2021**.

IVM 2015. Oosterhuis F., and Brouwer R. Benchmark development for the proportionality assessment of PBT and vPvB substances. *Institute for Environmental Studies (IVM)*. 2015

Kroes R., Renwick A.G., Feron V., Galli C.L., Gibney M., Greim H., Guy R.H., Lhuguenot J.C., and van de Sandt J.J. Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients. *Food and Chemical Toxicology*. **2007** Dec;45(12):2533-62.

Kulik F.A., and Ross W.D. Report. Salmonella mutagenicity assay of HB-40. Testing facility: MRC-Dayton for DMEH-St Louis. Report date: 1978-12-05. Report number: MRC-DA-835. *Study sponsor: Solutia*. Study number: DA-78-184. **1978**.

MITI 2004. Information on bioaccumulation in carp. *Email A. Kultamaa on 23.01.2008*. **2004** (secondary source cited in respective IUCLID RSS)

Moh M.H., Tang T.S., and Tan G.H. Determination of partially hydrogenated terphenyls-based thermal heating fluid in vegetable oils by HPLC with fluorescence detection. *Journal of the American Oil Chemists' Society*. Vol. 79, no. 4: 379-382. **2002**.

Monsanto. The Cumulative toxicity of HB-40. Report number: 48. Study number: KE-00-48.

Monsanto 1986a. Report. A thirteen week inhalation toxicity study of Therminol 66 in the rat. Testing facility: Bio/dynamics, Inc., Mettlers Road in East Millstone, New Jersey 08873. Report date: 1986-05-27. Report number: 84-7734. *Study sponsor: Solutia*. Study number BD-84-309. **1986**.

Monsanto 1986b. Report. An assessment of the mutagenic potential of Therminol 66 utilizing the acute in vivo rat bone marrow cytogenetics assay. Testing facility: SRI International, Ravenswood Ave. 333, Menlo Park, CA 94025. Report date: 1986-01-20. Report number: LSC-8019-002. *Study sponsor: Solutia*. Study number: SR-84-415. **1986**.

Monsanto 1985a. Report. A two-week dietary range-finding toxicity study of Therminol 66 in rats. Testing facility: Bio dynamics Inc., Mettlers Road, East Millstone, New Jersey 08873. Report date: 1985-07-29. Report number: 84-2855. *Study sponsor: Solutia*. Study number: BD-84-258. **1985**.

Monsanto 1985b. Report. A range-finding study to evaluate the toxicity of Therminol 66 in the pregnant rat. Testing facility: Bio/dynamics Inc., P.O. Box 43, East Millstone, New Jersey 08873. Report date: 1985-07-08. Report number: 84-2806. *Study sponsor: Solutia*. Study number: BD-84-067. **1985**.

Monsanto 1984. Report. A three-month oral toxicity feeding study in rats with Therminol 66. Testing facility: Bio/dynamics, Inc., Mettlers Road, P.O. Box 43, East Millstone, New Jersey 08873. Report date: 1984-09-17. Report number: 84-2869. *Study sponsor: Solutia*. Study number: BD-84-360. **1984**.

Monsanto 1982. Report. The hepatocyte primary culture DNA repair assay on compound NBP 2087922 using rat hepatocytes in culture. **1982**.

Monsanto 1981. Report. 21-Day Dermal Toxicity Study in Rabbits. Testing facility: International Research and Development Corporation MATTAWAN MICHIGAN, U.S.A 4907. Report date: 1981-10-14. Report number: 401-110. *Study sponsor: Solutia*. Study number: IR-79-356. **1981**.

Monsanto 1980. Report. Acute Toxicity of XA2020 to Daphnia magna. *Monsanto Industrial Chemicals Company*. Report number: ED-80-SS-15. **1980**.

Monsanto 1979. Report. Six-month chronic aerosol inhalation toxicity study with Santosol 340 in monkeys, rats, and hamsters. Testing facility: Industrial Bio-Test Laboratories, Inc., 1800 E. Pershing Road, Decatur, Illinois 62526. Report date: 1979-06-06. Report number: 8562-06032. *Study sponsor: Solutia*. Study number BTL-74-84. **1979**.

Monsanto 1976. Report. 30-Day pilot aerosol inhalation toxicity study with Santosol 340 in rats. Testing facility: Industrial Bio-Test Laboratories, Inc., 1810 Frontage Road, Northbrook, Illinois 60062. Report date: 1976-09-20. Report number: 8562-06031. *Study sponsor: Solutia*. Study number: BTL-74-82. **1976**.

Monsanto 1972. Report. 10-week subacute oral toxicity with Therminol 66 heat transfer liquid in albino rats. Testing facility: Industrial Bio-Test Laboratories, Inc., 1810 Frontage Road, Northbrook, Illinois 60062. Report date: 1972-09-14. Report number: B1312. *Study sponsor: Solutia*. Study number: BTL-72-21. **1972**.

Monsanto 1970. Report, secondary source. *Monsanto Company Organic Chemicals Division Applied Sciences Section*. Report number AC-71-SS-4. **1970**.

Monsanto. Report. Ultimate Biodegradation screening of XA-2020. *Monsanto Industrial Chemicals Company. Environmental Sciences Section – NIB*. Report number ES-80-SS-34.

Mostert, V., and Goergens, A. Dermal DNEL setting: using QSAR predictions for dermal absorption for a refined route-to-route extrapolation. http://www.toxicology.org/AI/PUB/Toxicologist11.pdf *Toxicologist*. ISSN 1096-6080, 120(2): 107. **2011**.http://www.toxicology.org/AI/PUB/Toxicologist11.pdf

Naylor M.W., and Ruecker F.A. Report. Two generation reproduction study of Therminol 66 Heat Transfer Fluid in the diet of albino rats. Testing facility: Monsanto Agricultural Company, Environmental Health Laboratory, 645 S. Newstead, St. Louis, Missouri 63110. Report date: 1991-10-09. Report number: MSL-11457. *Study sponsor: Solutia.* Study number: ML-90-135. **1991**.

NILU 2018. Screening program 2018. Volatiles, Gd, BADGE, UV filters, Additives, and Medicines. https://www.miljodirektoratet.no/globalassets/publikasjoner/m1490/m1490.pdf *Norsk institutt for luftforskning (NILU) and Norsk institutt for vannforskning (NIVA)*. **2018**.

NLM 2021. Compound summary for Diphenyl ether in PubChem. https://pubchem.ncbi.nlm.nih.gov/compound/Diphenyl-ether *National Library of Medicine*. Last access October **2021**.

Pirobloc 2021a. Thermal fluid systems. https://www.pirobloc.com/en/thermal-fluid-systems/ *Pirobloc website*. Last access October **2021**.

Pirobloc 2021b. Hot oil heaters and thermal fluids: the complete guide. https://www.pirobloc.com/en/hot-oil-heaters-and-thermal-fluids-guide/ *Pirobloc website*. Last access October **2021**.

Powell R.L., and Moser E.M. Report. The Toxicity of Therminol 66 (Partially Hydrogenated Terphenyls CAS # 61788-32-7) to Daphnia magna. *Monsanto Industrial Chemicals Company*. Report number: ESC-9646; MSL-14770. **1996**.

Renaudette and Adams. Report. A comparison of the sensitivity of Dahnia magna (waterflea) to Chironomus Tentans (Midge) for Seventeen Chemicals. *Monsanto Industrial Chemicals Company*. Report number: ESC-EAG-SS-84-15. **1984**.

Rice J. O`H. Report. Four-day static fish toxicity studies with Therminol 66 in Rainbow trout and bluegills. *Industrial Bio-Test Laboratories, Inc*. Report number: BTL 72-34. **1972**.

RIVM 1994. SimpleTreat. Assessment tool for the fate of substances in waste water treatment plants. https://www.rivm.nl/en/soil-and-water/simpletreat *Nederland National Institute for Public Health and the Environment*. Version used: 3.0. **1994**.

Saeger et al. Report. Comparison of environmental properties of cereclor 42 and santosol 340. *Monsanto Industrial Chemicals Co*. Report number AC-77-SS-6. **1977**.

Saeger et al. Report. Biodegradability of Santosol 300. *Monsanto Industrial Chemicals Co*. Special study 72-5. **1972**.

Saeger and Tucker. Report. Biodegradation testing of isopropylated biphenyl (MIPB) and HB-40. *Monsanto Company Organic Chemicals Division Applied Sciences Section*. Report number 1348006. **1970**.

Sasol 2019. Technical data sheet for 154L Specialty Alkylate. English version. https://sasoldcproducts.blob.core.windows.net/documents/Technical%20Datasheets/8ffcb411-5456_US_V-154L%20SPECIALTY%20ALKYLATE_EN-US.pdf *Sasol*. Date: 25.03.**2019**.

Schlechtriem C., Böhm L., Bebon R., Bruckert HJ., and Düring RA. Fish bioconcentration studies with column-generated analyte concentrations of highly hydrophobic organic chemicals. *Environmental Toxicology and Chemistry*. **2017** Apr;36(4):906-916.

Schroeder R.E., and Daly I.W. Report. A teratology study in rats with Therminol 66. Testing facility: Bio/dynamics Inc., P.O. Box 43, East Millstone, New Jersey 08873. Report date: 1986-02-17. Report number: 84-2807. *Study sponsor: Solutia*. Study number: BD-84-068. **1986**.

Solutia 2019. Chemical Safety Report of Terphenyl, hydrogenated. Update (v6) 2019-06-28. *Solutia UK Limited*. 2019.

Solutia 2018. Comparative environmental risk assessment. Terphenyl, hydrogenated. Unpublished report. *Solutia*. **2018**.

Steinmetz K.L. and Mirsalis J.C. Report. Evaluation of the potential of Therminol 66 to induce unscheduled DNA synthesis in primary rat hepatocyte cultures. Testing facility: SRI

International, Ravenswood Ave. 333, Menlo Park, CA94025. Report date: 1985-04-08. Report number: LSC-7576. *Study sponsor: Solutia*. Study number: SR-84-252. **1985**.

Sturaro A., Parvoli G., Rella R., and Doretti L. Hydrogenated terphenyl contaminants in recycled paper. *Chemosphere. Elsevier Science Ltd*. Vol. 30, No. 4, pp. 687-694. **1995**.

Tan N. Dr. Ir. Report. Determination of the aerobic degradation rate and route of (Phenyl-14C(U))-P-dicyclohexylbenzene in soil. *Notox BV*. Report number 489628. **2009**.

TGD. Technical Guidance Document on Risk Assessment. Institute for Health and Consumer Protection. TGD Part III. https://publications.jrc.ec.europa.eu/repository/bitstream/JRC23785/EUR%2020418%20EN-3.pdf *European Chemicals Bureau*. **2003**.https://publications.jrc.ec.europa.eu/repository/bitstream/JRC23785/EUR 20418 EN-3.pdf

Thompson Q. Biphenyl and Terphenyls. *Kirk-Othmer Encyclopedia of Chemical Technology, New York, John Wiley & Sons, Inc*., pages 8–9. **1992**.

Thompson C.M. Report. Acute Toxicity of Therminol 66 (AB-79-1384353-1a) to Fathead Minnows (Pimephales promelas). *Analytical Bio Chemistry Laboratories*. Report number: 23246. **1979**.

Tobor-Kaplon M.A. Report. Daphnia magna, reproduction test with Therminol 66 (semi-static). *WIL Research Europe B.V*. Project number: 504590. **2014**.

Tukes 2020. Analysis of the most appropriate risk management option (RMOA) for dibenzylbenzene, ar-methyl derivate (EC 258-649-2) and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (EC 400-370-7). https://echa.europa.eu/es/rmoa/-/dislist/details/0b0236e1834a0ed6 *Turvallisuus- ja kemikaalivirasto (Tukes)*. **2020**.

Tukes 2018. Annex XV report 'Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH article 57' for Terphenyl, hydrogenated. https://echa.europa.eu/documents/10162/3c36efa2-f86b-5065-1fbe-eb60459b4806 *Turvallisuus- ja kemikaalivirasto (Tukes)*. **2018**.

Weltens R. Report. Environmental assessment study: Growth inhibition test Pseudokirchneriella subcapitata. *Vlaamse Instelling voor Technologisch onderzoek (VITO)*. Report number: ALGE 10 035. **2010**.

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APPENDICES

Appendix 1:

Exposure/Emissions Questionnaire (Source: LR, 2018)

Extended questionnaire regarding Identified Uses of the substance (Human Health and Environment)

Substance	Terphenyl, hydrogenated

Downstream User XY is using Substanze "Z" as a heat transfer fluid (HTF, PC 16) for Biofuel Manufacturing. This can be considered as one Identified Use. By doing this, the HTF containing 50% of Substanze "Z" is filled into the HT system from drums (PROC 8b). Prior to the transfer, the HTF is stored in a closed system (e.g. PROC 1). Industrial workers, who are responsible for performing these processes are wearing a respirator (estimated efficiency: 90 %) and gloves conforming to EN 374 (estimated efficiency 95 %) as hygiene standard. While storage is a continuous process, the HTF transfer is happening within 45 min. The processes are performed at a temperature of 20-25°C. All processes are performed indoors where basic general ventilation (1 - 3 Air changes per hour) and Local exhaust ventilation take place.
Measured data at these workplaces are not available. This example could be also extended by integrating further information on the system in which the HTF is used. This could compromise information on sampling, re-filling procedures, equipment cleaning as well as waste management (end of service-life). Please inetegrate all relevant activities from the initial use of the substance/product until its waste life.

Example 2
The Substance "Z" is used as heat transfer fluid (HTF, PC 16) for Biofuel Manufacturing. In this case, ERC 7 (Use of functional fluid at industrial site) represents the most suitable release category for the Identified Use "Heat transfer fluids" which defines specific (conservative) environmental releases. However, estimated releases to the different compartments can be provided as well. These release estimations are based on the technical measures and/or Operational Conditions (OCs) which are further specified in the example table below. In case you can estimate how much of the substance used in one year is released into air/water/soil, please fill out the respective cells (column E-G). If you cannot estimate releases of the substance into the environment, please leave this fields empty.

In case different life-cycle stages are relevant for your company (e.g. use as HTF with its respective service-life) and environmental emissions differ, please indicate this in the questionnaire.

				Estimated release to environmental compartment			AIR - Type of RMM		WATER - Type of RMM		SOIL - Type of RMM			
Identified Use Name	Complete tonnage	Number of sites	ERC	Air [%]	Water [%]	Soil [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Remark on environmental releases (incl. wastelife)	General remarks / Monitoring data
Example: ES2 (IS): Heat transfer fluids	50 tonnes/year	1	ERC 7 (Use of functional fluid at industrial site.)	2	0	0	Collecting and condensing of vented products	Default value: 98 % (max. achievable: 99 %)	no wastewater produced; wastewater during equipment cleaning is incinerated	not applicable	Substance is only handled indoors and direct release to soil can be exclused. Installation outside (e.g. pump groups) are on sealed surfaces.	not applicable	only negligible amounts of the substance may be released into air; environmental released to wastewater and soil can be excluded; used HTF are always incinerated according to local legislation	-

Please enter relevant information here

				Estimated release to environmental compartment			AIR - Type of RMM		WATER - Type of RMM		SOIL - Type of RMM		Additional remarks	
Identified Use Name / Exposure Scenario	Complete tonnage	Number of sites	ERC	Air [%]	Water [%]	Soil [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Technical and operational measures	Typical efficacy [%]	Remark on environmental releases (incl. wastelife)	General remarks

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Appendix 2:

Questionnaire on Socio-Economic Impacts (Source: LR, 2018)

February 28, 2018

Glossary:

ALARA:

An acronym for „As Low As Reasonably Achievable" ALARA is an approach that aims to maintain the level of exposure to hazardous chemicals as far below regulatory limits as possible. It aims to achieve the lowest possible dose to the workers, the population or the environment.

Alternative Substance:

Alternative substances are defined as safer chemicals which are replacing more hazardous substances. This kind of substitution can bring substantial benefits for the company itself, the environment and the health of workers and consumers.

Authorisation:

Authorisation is a process within the REACH regulation that aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. It is a complex procedure which includes public consultations and time-limited authorisations for substances included in the process. Authorisation are applied for by industry.

https://echa.europa.eu/substances-of-very-high-concern-identification-explained

Exposure:

Chemical exposure can be defined as the measurement of both the amount of, and the frequency with which, a substance comes into contact with a person or the environment.

Restriction:

Restrictions are an instrument within the REACH regulation for risk reduction in order to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures for exposure minimization, specific labelling or restrictions in uses. Restrictions are carried out by the regulatory bodies.

https://echa.europa.eu/regulations/reach/restriction

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SME:

Small and medium-sized enterprises (SMEs) are defined in the EU recommendation 2003/361. The main factors determining whether an enterprise is an SME are:

- **staff headcount**
- either **turnover** or **balance sheet total**

Company category	Staff headcount	Turnover	or Balance sheet total
Medium-sized	< 250	≤ € 50 m	≤ € 43 m
Small	< 50	≤ € 10 m	≤ € 10 m
Micro	< 10	≤ € 2 m	≤ € 2 m

These ceilings apply to the figures for individual firms only. A firm that is part of a larger group may need to include staff headcount/turnover/balance sheet data from that group too. For more details: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

I. Company description

1. Please indicate the industry sector that you are representing. Use NACE nomenclature from below:
http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Business_economy_by_sector_-_NACE_Rev._1.1

II. Type of company

2. Please indicate whether your company is considered a SME (*small and medium enterprise)* in the EEA. (See Glossary above for definitions.)

Yes	No

III. Use of Substance

3. Please explain how you use the substance and in what application. Tick box in case application is mentioned below.

Heat Transfer Fluid Biomass	Heat Transfer Fluid Aluminum	Heat Transfer Fluid Chemical Industry/PET	Heat Transfer Fluid Bakery/Food	Heat Transfer Fluid Others	Coatings	Others

Please describe Use in case application was not mentioned above and add further details.

In case of "Others", please specify with short description (e.g. Use as a plasticizer in paints; use as a HTF in pharma industry):

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In case of use as Heat Transfer Fluid (HTF), please add relevant temperature range: °C =

4. Please explain the benefits of the substance for your business.
(e.g. mention the reason you are using this Eastman product):

5. Please indicate the number of your employees exposed to or handling the substance in 2017 in the EEA (European Economic Area = EU + Iceland, Liechtenstein and Norway).

0	**1 – 5**	**5 - 10**	**10 - 50**	**50 – 100**	**>100**

6. Please indicate your turnover generated on products produced in the EEA (European Economic Area) using the substance in 2017 and your estimate of the total market size (in €) for products produced in the EEA using the substance in 2017

Your turnover concerned by the substance **in the EEA in 2017**	**Total market concerned by the substance** **in the EEA in 2017**

IV. Most plausible reaction and criticality

7. How important is the substance for your operations?

Extremely Important	**Important**	**Less Important**	**Do not know**

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8. Suppose that the substance was to be phased out or its continued use subject to REACH Authorisation, what would be the most likely impact to your company? Please estimate the split of the turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA between options indicated below.

	Use of an alternative substance	**Business termination in the EEA**	**Business reallocation outside the EEA**
Phase Out: **% of the turnover generated using the substance in the EEA**			
REACH Authorisation: **% of the turnover generated using the substance in the EEA**			

9. If the substance is phased out or authorisation of the substance would force your company to terminate and reallocate your business, please explain why.
(e.g., why could you not further operate your business?):

10. If in question 8 you did not attribute any share of your turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA to the REACH Authorisation application, please explain why.

11. Suppose that the continued use of the substance would require complying with a REACH Restriction imposing release limit **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA), determined in the REACH registration dossier of Terphenyl, hydrogenated. Please estimate the split of your turnover of products manufactured with the use of Terphenyl, hydrogenated generated in the EEA between options indicated below.

	Continued use of the substance	**Use of an alternative substance**	**Business termination in the EEA**	**Business reallocation outside the EEA**
% of the turnover generated using the substance in the EEA				

12. If the REACH restriction imposing the aforementioned release limit (ALARA) would force you to terminate and reallocate your business, please explain why.

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V. Use of an alternative substance

13. Please indicate how you evaluate potential alternatives to the substance for your industry. Please evaluate their technical and economic feasibility and their fitness for use in your application.

Substance	**General assessment of the alternative**
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

14. Please provide a rough estimate of additional costs that you would encounter when switching to the alternative.

Substance	**Additional operating costs/annum (e.g. refills, top-ups)**	**Additional R&D and investment costs**	**Costs for structural alteration/ replacement measures**	**Cost resulting from yield losses**	**End-of-life costs**
Alternative 1 (please specify)					
Alternative 2 (please specify)					
Alternative 3 (please specify)					

15. Please explain your answer above - How would potential alternatives affect your product or operations performance, including costs?

Substance	Expected impacts on product and operational performance
Alternative 1 (please specify)	
Alternative 2 (please specify)	
Alternative 3 (please specify)	

VI. REACH compliance costs Restriction

16. Please indicate a rough estimate of compliance costs of the REACH restriction considered in this questionnaire.

REACH Restriction	Additional operating costs / annum	Additional R&D and investment costs
ALARA release limit		

17. Please explain why (if at all) your cost would increase under the considered restriction.

REACH Restriction with ALARA release limit	

VII. Lost jobs

18. How many jobs would you be forced to terminate in the EEA in each considered scenario?

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Number of lost jobs	**REACH Authorisation route**	**REACH Restriction with ALARA** **Release Limit**
0-10		
10-50		
50-100		
Other (include precise answer if available)		

19. Please explain what types of jobs would be lost in the EEA, in which regions and for what reasons.

REACH authorisation route		
REACH restriction with ALARA release limit		

VIII. Other effects

20. Please indicate any other information concerning that you consider relevant for the socio-economic analysis of the substance.

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Appendix 3

EU Commission Questionnaire on Socio-Economic Impacts (Source: ECHA, 2020, during SVHC Prioritisation Process)

PRIORITISATION

PUBLIC CONSULTATION ON SOCIO-ECONOMIC IMPACTS

The objective of this consultation is to inform policy makers about the economic and social consequences of the authorisation requirement. You are invited to provide specific information about the use of the substance and available alternatives, impacts on the environment, public health and society, and impacts on the supply chain and competitiveness.

This questionnaire contains 32 questions and is aimed at individuals, organisations, companies, as well as Member States. Due to the variation of the questions, it is possible that you are not able to answer to all of them.

Thank you for your contribution!

SUBSTANCE

1. What is the name of the substance on which you comment? Please specify if your replies concern more than one substance, e.g. a group of substances with similar uses.

USES

2. What is the use of the substance (sectors, types of uses, categories of products, etc.)?
   a. In general?
   b. By your company? *(only for companies)*

3. Can you specify the use in terms of volume/value?
   a. Overall in the EU?
   b. By your company? *(only for companies)*

4. Is the substance essential for certain uses (e.g. in terms of being indispensable for the product or process, for ensuring safety of the production process)? Which ones? Be specific on which property/function of the substance makes it essential.
5. Is the substance present in a finished article? If yes, at what concentration? Environment and Health?

6. Does the use of the substance imply any risks/exposure/releases for workers, consumers or environment?

7. What measures have been put in place to prevent these risks/exposure/releases?

8. How can exposure to workers or consumers be further reduced? How can releases into the environment be further minimised?

9. Are you aware of any relevant information (e.g. study or article) quantifying the cost of environmental or human health impacts related to the use of the substance?

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AVAILABILITY OF ALTERNATIVES

10. Are you aware about any alternative substances, processes or technologies currently available for the use(s) of the substance?
    a. If yes, what are these alternatives and where are they used?
    b. What are the main differences between using these alternatives compared to the substance in question?
    c. What are the hazard properties of the alternatives compared to the substance in question?
    d. Are the alternatives already available, i.e. drop-in alternatives? Or do their implementation require changes in the production process and investments?
    e. What is the expected price of alternatives, per unit (e.g. per kilo, tonne)?
    f. Would an alternative require the same, more or less volume (e.g. in kilos, tonnes) compared to the substance in question?

11. Would the use of these alternative substances, processes or technologies have a positive or negative impact, or no effect, on sustainability (considering the whole life cycle: manufacture of the substance/production/consumption/waste/recycling)?

12. Are you planning to substitute the substance? If so, by when? *(only for companies)*

13. Are there uses for which there are no alternatives (substances, processes or technologies)? If yes, could you explain why?

14. If there are no alternatives, are you aware of any research, development and innovation efforts attempting to develop them? If so, how long do you expect that the development / testing can take?
    a. In the EU or in non-EU countries?
    b. By your company? *(only for companies)*

MARKET AND SUPPLY CHAIN

15. Specifying the use of the substance, both overall in the EU and by your company, what is the annual volume/value of the substance:
    a. Placed on the EU market?
    b. Manufactured in the EU?
    c. Imported into the EU?
    d. Exported from the EU?

16. Could you specify the sector in which the substance is used and describe the supply chain, including your role in the supply chain?

17. Can you provide data on the turnover of the concerned sectors and the number of people employed? What is the turnover of the substance/substance-related products vs. the total turnover of the sector?

18. Can you estimate the relative weight of SMEs in the concerned sectors (in terms of number of companies and employment) in your country /in the EU?

19. Are the manufacturers of the substance or downstream users concentrated in a single/limited number of Member States or in a limited number of regions?

COMPETITIVENESS

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20. What would be, or has been, the overall cost and time of substitution for the particular use you are providing information on? This includes (if relevant) the need of changes in the production process, need for new product testing, qualification and certification, etc.

21. What is the expected impact of substitution costs on the costs of your inputs or final products? What is expected impact on your sales in the EU/outside the EU countries? *(only for companies)*

22. Please describe the typical length of the order cycle / investment cycle.
    a. To the concerned sectors?
    b. To your company? *(only for companies)*

23. Please describe what the impacts of including the substance in Annex XIV of REACH would be? This includes changes in the competitive position with respect to non-EU competitors in the EU market and in third markets.
    a. To the concerned sectors?
    b. To your company? *(only for companies)*

OTHER IMPACTS OF INCLUSION IN ANNEX XIV (innovation and business opportunities)

24. If the substance is included in Annex XIV to be eventually phased out, would it create business opportunities (e.g. gaining new markets or higher market share, development of alternative substances / products / production techniques)?
    a. In your sector?
    b. For your company? *(only for companies)*

25. What effects do you expect on enterprises' capacity to innovate? (The capacity to produce more efficiently and higher quality and a larger scale of products and services and the capacity to bring R&D to the market)

26. Are you aware of any likely effects on recycling or sustainability?
27. In your opinion, if the substance is included in Annex XIV to be eventually phased out, would the economy, society or the environment be better or worse off (all factors considered)? Why?

APPLICATION FOR AUTHORISATION *(only for industry actors)*

28. If the substance is included in Annex XIV, would you consider applying for an authorisation? Are you aware if your suppliers/downstream users would consider to apply?

29. How would you envisage that the submission of an application for authorisation could be organised, considering your specific uses and the structure of the supply chain: would you envisage an application by manufactures/importers of the substance or formulators (upstream the supply chain)/ or applications by downstream users or a combination of all)?

30. What main challenges in preparing an application do you expect for your specific case? Would you envisage applying for your own uses or would you apply to cover uses of your downstream users? Would you apply jointly with other downstream users covering the same use?

REGULATORY OPTIONS

31. Do you consider that other regulatory options could better address the concerns for human health or the environment for which the substance is recommended for inclusion in Annex XIV? What are these regulatory options and why would they better address the concerns?

OTHER REMARKS

32. Would you like to provide additional comments/information on the possible socio-economic impacts?

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Appendix 4:

Questionnaire on Socio-Economic Impacts by Dossier Submitter (June 2021)

Questionnaire for Terphenyl, hydrogenated

I. Company description

1. Please provide identification information of your company in the EEA[116] and the relevant contact person.

Company Name	
Country	
Contact person name	
Role	
Telephone number	
e-mail address	

2. Please indicate the industry sector that you are representing. Use NACE nomenclature from:
[Archive: Business economy by sector - NACE Rev. 1.1 - Statistics Explained (europa.eu)]

Industry sector	
NACE code	
Additional information	

3. Please provide information on your company at the EEA level (use aggregated figures)

Total Turnover	
Total number of workers	
Is your company an SME[117]?	
Number of sites in the EEA in which PHT is handled (please specify country per site)	

[116] EEA: European Economic Area = EU + Iceland, Liechtenstein, and Norway. It is expected that all the replies to the following questions refer to this economic area.
[117] Small and Medium-sized Enterprise, according to the recommendation from the European Commission of 6 May 2003. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32003H0361

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II. Uses and volume

4. Please indicate volume of PHT used[118] in the past three years (expressed as tonnes per annum)

2018	2019	2020
Comments:		

5. Please indicate in which applications / sectors of use your company is using PHT, including estimated% of volume[119] used in each sector.

Sector of use	Estimated% of volume used		
	2018	2019	2020
Heat Transfer Fluid			
Plasticiser			
Coatings and sealants: industrial applications			
Coatings and sealants: aerospace applications			
Processing solvents / processing aids			
Laboratory chemicals			
Microscope immersion oils			
Articles (connectors)			
Articles (temperature controls and thermostats)			
Other (please specify):			

6. Is PHT present in finished articles? If 'Yes', at what concentration?

[118] It is assumed that your role in the supply chain is as DU of PHT; if you imported any volume of the substance in the past years, please provide information on imports in the "Comments" box.
[119] To be calculated as volume used in each sector, divided by total volume used (summation of values provided in question 4, per year).

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III. Economic information and alternatives

7. Please indicate relevant business indicators (please specify units in which data is provided, e.g., tonnes, k€, m€).

Business indicator	2018	2019	2020
Revenue linked to products manufactured involving the use of PHT			
Net profit (after taxes) linked to products manufactured involving the use of PHT (please specify parameter used)			
% of your company's business linked to products manufactured involving the use of PHT (e.g., ratio between revenue obtained from PHT and total company revenue)			
EEA market share (%) of your company for products manufactured involving the use of PHT			

8. In addition to the economic information provided above:
   a. How would you describe the importance of the use of PHT for your business?

Extremely Important	Important	Not very important

   b. If you have answered "extremely important" or "important", could you please provide further details, if possible, in terms of why PHT is critical for your business?

In order for an alternative to be considered viable, it must be technically and economically feasible, provide an equivalent level of performance, be available in sufficient quantity when needed by industry, and it has to result in overall reduced risk compared to the chemical of concern. Alternatives may involve replacement of a chemical by another chemical, or by a combination of chemicals, or by switching to different technologies. If an alternative is not considered viable at present time, it needs to be evaluated if it is expected that it will become viable in the future.

9. Please provide information related to activities developed by your company, aimed at finding or introducing alternatives to the use of PHT, including investment and duration

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10. Please indicate how you evaluate potential alternatives[120] to the use of PHT for your specific use(s) in the table below, according to the following parameters.

a) Technical viability: describe if the alternative can be used for the required technical function at your site. Indicate if differences in performance are expected that would render the alternative unacceptable for your use, also if any tolerances for performance deviation are established in order to justify the answer.
b) Economic feasibility: describe if the implementation of the alternative would be justified from a business perspective, and if this can be done without business disruption. Provide details on costs that the company would need to face if the alternative were to be implemented (e.g., raw material costs, plant modifications, training of staff, investment cycle, etc.).
c) Risk/Regulatory comparative: Evaluate potential risks for human health and the environment for the alternatives; are they regulated equally to PHT, or can it be expected that they will be in the future?
d) Time to implementation: if it is not possible to implement an alternative now, but it could be possible in the future, provide a justified timeline for the implementation.

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[120] Even if an alternative is not considered to be viable based on the description provided at the beginning of this section, its characteristics should be described, to provide evidence that a proper assessment of alternatives has been made.

Alternatives[121]	General assessment of the alternative
Alternative 1 (describe alternative and technical function)	Technical viability:
	Economic feasibility:
	Risk/Regulatory comparative:
	Timeline to implementation (if feasible):
Alternative 2 (describe alternative and technical function)	Technical viability:
	Economic feasibility:
	Risk/Regulatory comparative:
	Timeline to implementation of alternative (if feasible):

11. If you were forced to substitute PHT from use in your processes, what do you think would be the consequence for your company? Please mark with "X" the option that

[121] If more alternatives have to be assessed, please add rows, or provide more copies of the current page as needed.

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you believe is more likely. If possible, specify in the box below how many jobs would be lost in the EEA in case of termination of business in the region, or what would be the expected cost and time for implementation of an alternative.

Switch to alternative substances	**Business reallocation outside EEA**	**Company would abandon business related to PHT globally**

12. If the use of PHT was to be allowed under conditions that would imply the adoption of additional technical measures[122], would it be possible to establish a limit of investment that would be acceptable to your company to continue the business?

13. Please indicate any other information of concern, or that you consider relevant for the socio-economic evaluation of PHT, keeping in mind indirect impacts for the EU economy, environment, and society (e.g., impact on capacity for innovation, impacts on environment due to more/less efficient processes, increased/decreased costs of products, etc.).

IV. Emissions and exposure

14. Are environmental emissions from PHT adequately controlled from your use of the substance? Please provide information, detailing what containment systems are in place to ensure that releases of PHT are minimised. For example, for Heat Transfer Systems the following should be considered.
    a. Existence of collection vessel.
    b. Performance of tests to prove the suitability of joints.
    c. Use of containment devices installed beneath flanges and pumps
    d. Use of an inert gas as protection of the fluid against oxidation.
    e. Periodical evaluation of the fluid quality (please, specify frequency).

[122] For Heat Transfer Systems, a valid reference on technical standards that could be required for operating HTS is the German Industry Standard DIN 4574 – more information on Section VI

f. Use of pumps with mechanical seals.
g. Use of valves with mechanical seals.
h. Repetitive inspections performed by competent technical bodies.
i. Control programs for potential leakages.
j. Fluid level monitoring.
k. Specific detail on containment measures would be useful for:
    - Drain of PHT
    - Fill and top-up of PHT
    - Disposal of degraded PHT

15. For Heat Transfer Systems, have any of the following Standards and Regulations been considered during design, construction, and operation of the HTF system?

	Considered?
General Product Safety Directive 2001/95/EC	
Pressure Equipment Directive 2014/68/EU	
German Industry Standard DIN 4754	
Other National Standards and Regulations (please, specify)	

16. For Heat Transfer Systems, please provide information on the following parameters:

	HTS 1	HTS 2	HTS 3
Operating temperature			

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Pressure			
Volume of PHT used			
Time of service of HTF system			

17. Please provide information on disposal of PHT, indicating volumes disposed of and how frequently disposal occurs, as well as destination of disposed product.

18. Do you have any information or approximate indication about yearly emissions of PHT to different environmental compartments (e.g. soil, air, water)?

19. Please provide any further information that you consider relevant for the purpose of controlling emission of PHT to the environment.

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Appendix 5:

How to reach the Strictly Controlled Closed System (SCCS) condition in heat transfer systems using Terphenyl, hydrogenated as HTF

Executive Summary

The REACH restriction on Terphenyl, hydrogenated outlines two options (RO1 and RO2) which derogate heat transfer fluid (HTF) uses at industrial sites if such sites implement strictly controlled closed systems (SCCS). This document aims to ensure an adequate level of technical preparation and design of a plant to guarantee an elevated level of protection against environmental releases. The document can be applied to other organic HTFs similar to Terphenyl, hydrogenated if REACH Restrictions are introduced for other HTFs.

As the term SCCS is not defined yet, this document aims to establish clear instructions for downstream users to ensure continued safe use of the substance and enable authorities to be able to verify compliance with these conditions during inspections. The document aims to develop the SCCS condition by taking references and combining criteria from existing EU Legislation or official EU Guidance Documents, including:

- Strictly Controlled Conditions (SCCs)
    - ECHA Practical Guide 16 (ECHA, 2014)
    - REACH Article 18
- CMR Directive (Article 5) on the prevention and reduction of exposure via closed systems
- The IPPC Directive, including Best Available Techniques (BAT), as outlined in the BAT Reference Document (BREF) on i.e., Production of Polymers (COM, 2007)
- Seveso Directive
- European Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (Pressure Equipment Directive – PED)
- German Standard DIN 4754-1 (DIN, 2015), 'Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test'
- US Standard NFPA 87 (Standard for Fluid Heaters)
- References and documents on HTF Systems from the Employers Mutual Insurance Association (Berufsgenossenschaft Rohstoffe und Chemische Industrie), the German Legal Accident Insurance (DGUV) and the Risk Engineering Guideline from Insurer HDI
- Operational procedures from existing restrictions (e.g., Isocyanates) or the Guideline for industrial users of 1-methyl-2-pyrrolidone (NMP) to help them comply with the substance's restriction requirements (ECHA 2020; ECHA, 2019)

This document covers:

- Design and construction
- Fill & Start-Up (unloading & loading)
- Operation & Maintenance (incl. storage)
- Dismantling/Decommissioning & Waste
- Inspections & Training

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The document contains in an Annex an Inspection Check List to enable control of the Heat Transfer Systems designed to achieve the SCCS condition and the enforceability of the criteria.

1. Introduction

1.1. For whom is this document written?

This document is addressed to HTF downstream users (DUs) of Terphenyl, hydrogenated in order to provide practical advice and assist users in complying with their obligations under the HTF Derogation of Terphenyl, hydrogenated within the Terphenyl, hydrogenated Restriction. It is furthermore addressed to enforcement authorities in order to verify compliance during inspections. The attached inspection checklist will be an extremely useful tool to audit compliance on-site.

The basic concept of this document, particularly related to the case of HTF, is to demonstrate enclosure, avoidance of leakages and releases to the environment. An adequate level of technical preparation and design of a plant to guarantee elevated level of protection against environmental releases is lacking under the SCC descriptions. Therefore, this document intends to combine the different elements in one document.

This document applies to heat transfer installations in which Terphenyl, hydrogenated is used as a Heat Transfer Fluid, heated to temperatures below or above its initial boiling point at atmospheric pressure. The installations shall be designed and constructed (new installations), adapted (existing installations), and operated according to the technical requirements and operational procedures as outlined in this document in order to assure their technically tightness and that they remain technically tight.

The operator of each HTF plant shall ensure that the equipment is provided and operated in such a way that they safely withstand the mechanical, chemical, and thermal stresses to be expected due to the intended mode of operation in order to avoid any releases and exposure.

Compliance with this document will be mandatory for all current and future installations to comply with the derogation conditions of the HTF use in the Terphenyl, hydrogenated restriction.

The general approach described in this document can be applied to other organic HTFs, alike to Terphenyl, hydrogenated, if similar REACH Restrictions are introduced for other HTFs.

1.2. The restriction proposal

Restriction Options RO1 and RO2 include a derogation that shall apply for the use of Terphenyl, hydrogenated as HTF at industrial sites, provided that such sites implement strictly controlled closed systems with technical containment and other measures, to minimise environmental emissions.

However, as the term **Strictly Controlled Closed Systems (SCCS)** is not defined yet, it will be difficult for plant operators and enforcement authorities to verify compliance with these conditions.

The term "*Strictly Controlled Closed System*" was introduced into REACH via the Restriction of the Siloxanes (D4, D5, D6)[123] as outlined below:

"*The use of D5 is under Restriction Condition 6.a derogated from the restriction in strictly controlled closed dry-cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated and are only permitted when strict operational conditions and risk management measures are adopted (e.g., use of closed systems).*"

According to the Final BD of the Siloxanes Restriction[124], the wording proposed should be interpreted by analogy to:

(i) the concept of Strictly Controlled Conditions (SCC) for Intermediates under REACH[125], and

(ii) from a derogation included in existing restriction entry forty-six in Annex XVII (on the use of nonylphenol for industrial washing and cleaning) (e.g., "*closed*" processes).[126]

The derogations in Entry 46 of REACH Annex XVII reads as follows:

…."controlled closed systems where the washing liquid is recycled or incinerated."

Unfortunately, no further technical description and process safety measures are provided.

1.3. The Guide on strictly controlled conditions

ECHA Practical Guide 16[127] (ECHA, 2014) sets out the requirements to verify whether a substance is used as an intermediate under Strictly Controlled Conditions (SCCs). The legal background is related to intermediates and their reduced information requirements, if managed under SCC.

As the use of Terphenyl, hydrogenated as HTF in heat transfer systems is not considered intermediate, this Guide cannot be considered completely appropriate to describe this use. However, it could be a good starting point for the definition of SCCS.

SCC are addressed in the law under REACH Article 18, as summarized below:

- the substance is rigorously contained by technical means during its whole life cycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

[123] Registry of restriction intentions until outcome - ECHA (europa.eu)
[124] Microsoft Word - REST_D4D5D6_FinalBD.docx (europa.eu)
[125] 291b6e50-5598-42d3-8a2b-d63d50a68104 (europa.eu)
[126] e5842a1e-e9f9-6096-2829-72f71c00eaab (europa.eu)
[127] 291b6e50-5598-42d3-8a2b-d63d50a68104 (europa.eu)

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- procedural and control technologies shall be used that minimise emission and any resulting exposure;
- only trained and authorised personnel manage the substance;
- in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
- substance-handling procedures are well documented and strictly supervised by the site operator.

SCCs under REACH are described as "*a combination of technical measures that are underpinned by operating procedures and management systems*" Those measures include:

- Rigorous containment of the substance by technical means, supported by procedural and control technologies in place, used to minimize emissions and resulting exposure (including during sampling, cleaning, and maintenance).
- Management systems in place, specifying that handling of the substance must be performed by trained, authorised, and supervised personnel in accordance with well documented procedures.
- Special procedures in place for cleaning and maintenance.
- Procedural and/or control technologies in place to deal with accidents, waste management and, in a more generic way, to minimise emissions and exposure.

The Guide on SCCs puts specific emphasis on the following additional items:

- Systems need to be designed with the objective of minimising exposure, including in loading and unloading operations. A number of options for this are provided, focused on enclosure and isolation.
- Ancillary equipment (pipelines, pumps) must be designed and installed in a way that will ensure containment at all times.
- Special procedures are expected for activities not directly related to the use of the substance, e.g., cleaning and maintenance and associated technical requirements (purging, washing). Also control of wastewater or air emissions from those activities have to be treated / collected in order to minimise eventual releases of the substance to the environment. Moreover, permit-to-work procedures need to be in place for these activities, in order to ensure that workers will always be aware of potential safety requirements of the operations.
- Although PPE can be used as "*good practice*" procedures, it has to be underlined that rigorous containment should be achieved without taking into account the use of PPE.
- The implementation of RMMs to control releases to the environment below threshold values (e.g., local PNEC) is not sufficient to justify SCCs. Technical measures have to be in place in addition to the regular emissions reduction measures in order to demonstrate that emissions are effectively minimised.
- Waste handling and management (including wastewater treatment plants – WWTP) is subject to the same requirements as handling of the substance under normal operations. Some specific indications related to waste collection are:

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   - Collection of waste in sealed drums in a dedicated filling station, equipped with glove box and an integrated LEV.
   - Collection of liquid waste in road tankers. Loading and unloading of truck tanks taking place in dedicated stations. Tanks to be provided with vapour recovery systems, connection of tanks to loading system through flexible hoses, using dry-break couplings. Hoses to be drained and purged before they are connected and/or disconnected. Systems are provided with integrated LEV or other air-dynamic barriers.
- Monitoring of the process for the presence of emissions and releases and measuring of the exposure of workers and/or the environment is one option to confirm the integrity and effectiveness of the rigorous containment methods that are implemented. In this regard, measurement of the (potential) releases of the substance to different environmental compartments may be required to demonstrate compliance with environmental legislation such as the IED Directive (Directive 2010/75/EU replacing the IPPC Directive)[128], water discharge permits and so on. Other adequate procedures are acceptable too.
- Suppliers of a substance that is intended to be used under SCCs has to recommend the relevant Risk Management Measures (RMMs) to its downstream users. In the case of terphenyl hydrogenated, it is clear that it would be for the user to apply SCCs or any equivalent level of protection. It would be recommendable for the user of terphenyl hydrogenated to confirm in writing to the permitting authority of the HTF plant that they abide to the relevant RMMs and the requirements in this document.

1.4. Other reference documents

Moreover, there is other EU Legislation or official EU Guidance Documents which were used as valuable references for the definition of SCCS.

For example, the EU's **CMR Directive**[129] is addressing in Article 5 the prevention and reduction of exposure via closed systems. Unfortunately, this term is not included in the definitions.

The **IPPC Directive**[130], which in essence is about minimising pollution from various industrial sources throughout the European Union, was consulted too. The IPPC Directive is based on several principles, including Best Available Techniques (BAT), as outlined in the BAT Reference Document (BREF) on i.e., Production of Polymers (COM, 2007)[131] and is applicable to operators of industrial installations.

In addition, the **Seveso Directive**[132] (Directive 2012/18/EU) was used as a reference, which was enacted to prevent major accidents and to ensure appropriate preparedness and response should such accidents nevertheless happen.

Furthermore, the European Directive 2014/68/EU[133] on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment

[128] The Industrial Emissions Directive - Environment - European Commission (europa.eu)
[129] EUR-Lex - 02004L0037-20220405 - EN - EUR-Lex (europa.eu)
[130] EUR-Lex - 32010L0075 - EN - EUR-Lex (europa.eu)
[131] Production of Polymers | Eippcb (europa.eu)
[132] EUR-Lex - 32012L0018 - EN - EUR-Lex (europa.eu)
[133] EUR-Lex - 32014L0068 - EN - EUR-Lex (europa.eu)

(**Pressure Equipment Directive – PED**) was used as a reference. PED is applicable to Terphenyl, hydrogenated because for most of the systems the maximum allowable temperature of the HTF installations (325-350°C) exceeds the flashpoint of the substance (170°C), according to Point 1(a) of Article 13 to PED.

Besides, the **German Standard DIN 4754-1** (DIN, 2015)[134], 'Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test', was used. This standard applies to heat transfer appliances in which organic HTFs are being heated with atmospheric pressure to reach a temperature above or below their initial boiling point.

The document applies to heating appliances only as far as the pipes of the heater contain the HTFs. The document has the purpose of satisfying protection targets for the production and supply, in particular those specified in the PED.

The **US Standard NFPA 87**[135] (Standard for Fluid Heaters) was considered as well. It provides safety guidance for fluid heaters and related equipment to minimize fire and explosion hazards that can endanger the fluid heater, the building, or personnel to avoid leakages and thus emissions.

Moreover, references and documents on HTF Systems from the **Employers Mutual Insurance Association** (Berufsgenossenschaft Rohstoffe und Chemische Industrie)[136], the **German Legal Accident Insurance** (DGUV)[137] and the Risk Engineering Guideline from **Insurer HDI**[138] were consulted.

Finally, **operational procedures** from existing restrictions (e.g., **Isocyanates**[139]) or the **Guideline** for industrial users of 1-methyl-2-pyrrolidone (**NMP**) to help them comply with the substance's restriction requirements (ECHA 2020; ECHA, 2019)[140].

These legislations, guidelines, and standards shall be used as a basic requirement when designing, building, and operating new systems. In addition, existing systems must be assessed on a regular basis using the most up-to-date standards and to improve the structural and organisational matters if applicable.

2. Design and construction

The installations using Terphenyl, hydrogenated as HTF shall be designed and constructed (new installations) and adapted (existing installations) according to technical requirements and operational procedures as outlined in this document.

The installations shall comply with all of the applicable legislation in force, at the European, national, regional, and local levels, related to the design and construction of heat transfer systems, in order to assure that during operation the protection of human health and the

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[134] DIN 4754-1 - 2015-03 - Beuth.de
[135] NFPA 87: Standard for Fluid Heaters
[136] DGUV Regel 100-500 Betreiben von Arbeitsmitteln | DGUV Publikationen
[137] Microsoft Word - V_3.11 Sicherheitsbetrachtungen beim Betreiben von WÃ¤rmeÃ¼bertragungsanlagen mit organischen WÃ¤rmetrÃ¤gern.docx (bgrci.de)
[138] 20190305_403-HRC-REG130GB__heat_transfer_oil_systems.pdf (hdi.global)
[139] Registry of restriction intentions until outcome - ECHA (europa.eu)
[140] All news - ECHA (europa.eu)

environment is guaranteed. Specifically, the main European legislation to consider is the Pressure Equipment Directive – PED.

According to PED, the heat transfer system shall be designed, constructed, and equipped in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.

Furthermore, in order to achieve the SCCS condition, the complete heat transfer system installation (it means, all of the equipment involved in the process) shall be designed, constructed, and adapted to ensure rigorous containment of Terphenyl, hydrogenated, in order to minimise releases and, consequently, the possibility of exposure to the environment (ECHA, 2014). In fact, ECHA Guidance on intermediates (ECHA, 2010)[141] states that rigorous containment can be only achieved by the technical design of the equipment which aims at preventing releases. This design will consider the physico-chemical properties of Terphenyl, hydrogenated and the process conditions, and the release of Terphenyl, hydrogenated will be prevented through containment systems. In addition, plant components shall be considered to be technically leak tight if they are designed such that they remain technically leak tight due to their construction (BAUA, 2022).

All of the components of the heat transfer system, including heat exchangers, piping, insulation, pumps, valves, gaskets, seals, relief devices, and instrumentation, must be selected during the design process for compatibility with Terphenyl, hydrogenated and the intended system temperature and pressure. Any component not specifically suitable for Terphenyl, hydrogenated shall be used with extreme caution. In addition, the components of the system must accommodate all expected temperature extreme. Thermal growth in heat transfer systems operated with organic fluids requires careful study because they can experience larger temperature variations (GAP, 2013).

Therefore, it is important that, during the designing and building of the heat transfer system, the system designer and the Terphenyl, hydrogenated manufacturer are consulted for advice on the choice of, e.g., the gasketing material (for joints) and the packing material (for valves and pumps) that will provide the best leak-free service for Terphenyl, hydrogenated at the intended operating temperatures and pressures, and considering the operating environment, both internal and external (FM Global, 2022).

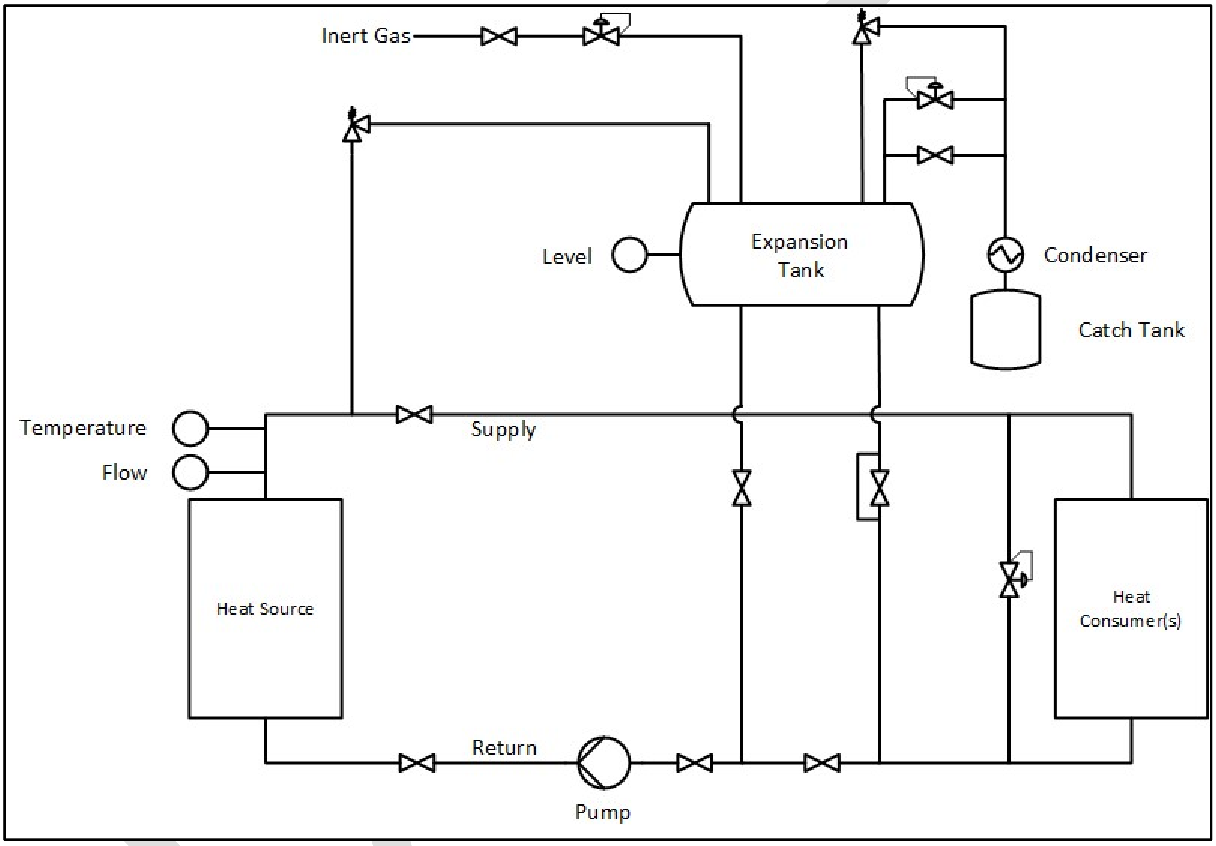
Although Terphenyl, hydrogenated is used in a wide number of sectors and settings, the heat transfer system installations are similar across industry sectors. For this reason, it is possible to establish general and common risk management measures through the design process (ECHA, 2019).

There are many technical means that can be considered during the design of the heat transfer system installations to prevent emissions by containment. Due to this fact, all of the reference texts considered in this document do not define any exhaustive list of equipment or technical requirements. As stated in German Standard DIN 4754-1 (DIN, 2015), deviations from its requirements are possible if it can be demonstrated that the safety standard of that standard is met in another way. In addition, the same standard provides that other requirements can

[141] https://echa.europa.eu/documents/10162/2324906/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641

be observed, as the specified in valid statutory regulations and regulations, as well as regulations of accident insurance institutions. Due to this, the technical means and equipment named in this section, and also in the other sections of this document, shall be considered exclusively as examples.
Non-pressurized HTF systems are operating below the boiling point of the fluid (like systems using Terphenyl, hydrogenated) but are still working under a system pressure which is greater than the atmospheric one. The pressure is typical a few bars. Therefore, they can only operate reliably and efficient if the plant is tight.

Figure 1: Schematic Heat Transfer Fluid System.



2.1. Heat transfer system area

The construction of the heat transfer system shall be conducted on an impermeable surface (e.g., concrete) to avoid soil contamination in case of potential emission, and to facilitate the cleaning and containment of the leakage.

The area under the system shall be coupled with sloped floors, and curbs, dikes, and controlled drainage systems must be designed to divert potential leakage and runoff to a safe location, to prevent a potential Terphenyl, hydrogenated spill from flowing into adjacent production areas, storage areas, or floors below (FM Global, 2022). Drainage to a waste treatment facility would be the ideal protection measure. However, at a minimum a dike at the thermal heater or boiler to contain Terphenyl, hydrogenated in this area is critical (GAP, 2013). In any case, the drainage of contaminated effluents must be stored in closed systems (COM, 2007).

2.2. Vessels and tanks

According to the generic BAT for equipment design described in the BREF for polymers (COM, 2007), the process vessels shall be equipped with vents to prevent pressure build up by inert gases. This is also a requirement of the PED in order to avoid harmful effects, such as water hammer, vacuum collapse, corrosion, and uncontrolled chemical reactions, and to permit cleaning, inspection, and maintenance in a safe manner. These vents are also used to depressurise and flush equipment during emergencies and prior to maintenance. The best option is that venting and expansion lines are routed into collection systems (BAUA, 2022) and connected to air pollution control equipment.

To prevent leaks from relief vents, rupture disks can be used in combination with safety valves. The pressure between the rupture disc and the safety valve is monitored to detect any leaks. If the safety valves are connected to an incinerator, rupture disks may not be necessary (COM, 2007).

An effective BAT is to design and construct calamity basins/tanks to control potential accidents during the processes involving high volumes of Terphenyl, hydrogenated that are out of the usual operational conditions (filling and drain). These tanks, used for the safe storage of escaping Terphenyl, hydrogenated, may be of metallic materials or other material, such as concrete with oil-repellent coating (DIN, 2015).

2.3. Piping and piping parts

The piping installation must be designed with appropriate and resistant materials to prevent breakages that could lead to environmental pollution (COM, 2007). Welded construction must be used whenever possible (GAP, 2013; DIN, 2015).

In addition, the thermal expansion must be taken into account by the appropriate routing of the piping or by installing suitable expansion joints (DIN, 2015). The number of flanges (connectors) must be minimised to avoid potential leaking points and to accommodate only fundamental/essential major equipment isolation and/or removal, and the gaskets must be effective (COM, 2007).

In order to prevent the escape of large quantities of Terphenyl, hydrogenated, stop valves in the flow and return pipes are to be installed. This is especially important in systems containing more than five tonnes of Terphenyl, hydrogenated. These stop valves are to be actuated from a safe position. The stop valves shall be of proven suitability, or their suitability shall be documented by providing the results of testing from the valve manufacturer or an accredited expert (DIN, 2015).

2.4. Pumps

In order to prevent and minimise emissions, the use of magnetically driven or canned motor pumps, or pumps with double seals and/or a liquid barrier is recommended (COM, 2007).

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The pump housings must be designed to withstand at least a maximum pressure of 16 bar. The shaft seals must be of proven suitability, or their suitability must be demonstrated, e.g., by submitting test results from the pump manufacturer or an accredited expert (DIN, 2015).

It must be ensured that potential heat transfer fluid leaks from the shaft seal are safely diverted and collected (DIN, 2015). Therefore, it is recommended that pumps are surrounded by curbs (FM Global, 2022).

2.5. Thermal insulation

At points where there is a risk of Terphenyl, hydrogenated leaking (e.g., at flange connections and fittings), the thermal insulation shall be designed in such a way that potential leaks can be detected with the lowest response timing (DIN, 2015).

2.6. Sampling points

In order to prevent and minimise emissions, special equipment shall be used at sampling points to ensure that only small quantities of Terphenyl, hydrogenated can escape (BAUA, 2022).

2.7. Other technically leak-tight plant components

Other components that can be included in the design and construction of heat transfer systems operating with Terphenyl, hydrogenated as HTF in order to prevent and minimise emissions to the environment are the following (COM, 2007; BAUA, 2022; DIN 2015):

- valves with bellow
- valves with double packing seals
- valves with sealing of the spindle feedthrough by means of bellows and safety stuffing box
- flanges with weld lip gaskets
- flanges with flat faces
- flanges with raised faces
- flanges with tongue and groove faces
- flanges with protrusion and recess
- flanges with V-grooves and V-groove gaskets
- flanges with smooth sealing faces and special gaskets (e.g., soft gaskets up to twenty-five bar, gaskets with metal inner rim, grooved gaskets, corrugated gaskets, or metal jacketed gaskets, if a mathematical check shows sufficient safety against the yield point when using standard flanges)
- flanges with smooth sealing strip and no special design requirements for the seal
- cutting and clamping ring connections
- shaft seals with double-acting mechanical seal
- shaft seals based on simple operating principles (e.g., single-acting mechanical seals or stuffing boxes)
- metal-sealed connections

In case this kind of components, or any of the other components listed in this section (e.g., pumps), cannot be considered during the design and construction stages of the heat transfer system using Terphenyl, hydrogenated as HTF, and standard components are used instead, containment devices shall be installed beneath them.

2.8. Control equipment and safety devices

The instrumentation, the control equipment, and the safety devices (e.g., Terphenyl, hydrogenated level monitors) shall be designed to ensure that the heat transfer system and the process remain safe (GAP, 2013)

3. Fill & Start-Up (unloading & loading)

The processes of filling, start-up, shutdown, and drain of the heat transfer system are out of the usual operational conditions of the installation. In the processes of filling and drain of the HTF, that can occur before the start-up and after the shutdown (respectively) of the installation, Terphenyl, hydrogenated is managed out of the heat transfer system. Therefore, these processes are potential emission sources of Terphenyl, hydrogenated and, for this reason, special containment measures shall be taken for their performance.

According to PED, the heat transfer system shall be provided with accessories to ensure safe filling and drain (discharge), in particular with respect to the following risks:

- On filling: overfilling or over pressurisation
- On drain: uncontrolled release of the fluid
- On filling or drain: unsafe connection and disconnection

A generic BAT in order to avoid potential emissions to the environment related to these processes is to minimise plant start-ups and shutdowns. This can be achieved through improved operation stability (assisted by monitoring and control systems) and equipment reliability. Emergency stops can be avoided by timely identification of deviating conditions followed by the application of a controlled shutdown process (COM, 2007).

The renewal of the Terphenyl, hydrogenated in the heat transfer system is required because the substance begins after many years in service to age (in some cases until 20-30 years), resulting in degradation products, an increase in viscosity, and solids may begin to form. Once the Terphenyl, hydrogenated quality has been analysed and found to be compromised, corrective actions have to be performed (e.g., partial or complete drain).

After the fluid has been cooled to a safe level, it can safely be drained via pumps, following appropriate written procedures, from the system into storage tanks for disposal. The removal of the fluid from the system as well as the fill with new Terphenyl, hydrogenated takes place in sealed and contained areas.

Filling and drain processes of Terphenyl, hydrogenated shall only be undertaken by qualified personnel (DIN, 2015).

During the period in which the installation is filled and started up, it is necessary to continuously monitor all connections, heat transfer system components, and pipes for leakages. Likewise, the pipeline network shall be controlled (e.g., the fixed and sliding supports) to ensure that it is correctly installed (VDI, 1995).

To ensure that the heat transfer system will be leak-free when filled and started up with Terphenyl, hydrogenated, it is recommended to conduct special leakage testing in addition to a general hydrostatic test. It has to be noted that a pipeline may pass a hydrostatic test and yet have leaks when the heat transfer fluid is used. The details of leakage testing procedures can be obtained from the system designer and manufacturer of Terphenyl, hydrogenated (FM Global, 2022). The most common and reliable leakage testing is the detection of leakages by painting joints (flanged or welded connections, etc.) with suitable wetting agents, e.g., soap solutions (VDI, 1995). This leakage detection testing can be performed by the procedures defined in the German standard DIN 4754 (DIN, 2015).

In order to facilitate the detection of leakages during filling and start up, thermal insulation shall not be applied in the potential leak points until after an operating period of about 30 to 50 hours has exposed and after the installation has been exposed to one or more heating/cooling cycles (VDI, 1995).

After each filling and start-up processes, the heat transfer system must be checked visually for leakages (VDI, 1995).

The control and testing procedures during shutdown and drain processes are equivalent to those set out above for filling and start-up processes.

4. Operation & Maintenance (incl. storage)

4.1. Operation

The heat transfer systems using Terphenyl, hydrogenated as HTF shall be operated according to technical requirements and operational procedures as outlined in the operational manual of the system designer and this document.

According to PED, the method of operation specified for the heat transfer system shall be such as to preclude any reasonably foreseeable risk in the operation of the equipment. In order to ensure that the heat transfer system and the process remain safe during operation, operating limits for temperature, pressure, Terphenyl, hydrogenated level, flow rates, and chemical composition of Terphenyl, hydrogenated shall be established for the heat transfer system and the process it serves (GAP, 2013).

The technical measures introduced during the design and construction stages, such as control engineering safety devices, aim at fully enclosing the system and avoiding emissions to the environment during operation. For their part, the organisational measures, such as written methods (operating procedures, working instructions, permits to work, etc.), aim to maintain the process conditions achieved by the technical measures.

Detailed written methods (procedures, instructions, and permits) for all normal and emergency operations shall be provided. These written procedures shall be supplemented with formal operator training programs for initial qualification and periodic refresher training

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(GAP, 2013). The existence of written procedures and instructions is also a requirement of some of the conformity assessment procedures applicable to pressure equipment according to PED.

The adoption and implementation of these written procedures, instructions, and permits for safe operation, constitutes the operation control of the heat transfer system. As stated in the Seveso Directive, the operational control includes:

- maintenance, of plant, processes, and equipment
- alarm management and temporary stoppages
- consideration of the available information on best practices for monitoring and control, with a view to reducing the risk of system failure
- management and control of the risks associated with ageing equipment installed in the establishment and corrosion
- inventory of the equipment, strategy, and methodology for monitoring and control of the condition of the equipment
- appropriate follow-up actions and any necessary countermeasures;

As defined in the Seveso Directive, storage means the presence of a quantity of substances for the purposes of containment , depositing in safe custody, or keeping in stock. In the case of the heat transfer systems operated as SCCSs (fully enclosed), the system itself acts as a warehouse for the Terphenyl, hydrogenated. Consequently, the technical and organisational measures implemented at the operational level guarantee that there are no potential emissions during storage.

4.2. Maintenance

The heat transfer systems using Terphenyl, hydrogenated as HTF shall be maintained according to technical requirements and operational procedures as outlined in the operational manual of the system designer and this document.

The plant components of a heat transfer system operated with Terphenyl, hydrogenated as HTF shall be considered to be technically leak tight if their technical leak tightness is continuously ensured by maintenance and monitoring (BAUA, 2022). This means that, in addition to the purely design, constructive, and technical measures, the organisational measures can also lead to a technically tight plant. These measures include the appropriate preventive maintenance program and the control of the installation through regular leak tightness checks on components (seals, flanges, pumps, etc.).

The scope and frequency of the measures to be taken in the course of preventive maintenance shall depend in detail on the type of design, mode of operation, stresses and strains, as well as the condition of Terphenyl, hydrogenated. These measures shall ensure technical tightness of the heat transfer system (BAUA, 2022). Care must be taken to ensure that the scope and frequency of the measures are specified in written documents (e.g., in operating instructions or in the maintenance program).

Control and safety devices must be checked for their effectiveness (DIN, 2015). Furthermore, the complete heat transfer system must be checked visually for leakages, within the recommended inspection intervals (VDI, 1995).

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The technically leak-tight plant components shall be checked for leak tightness, either as a whole or in affected sections, after any repair work. The appropriate procedure shall be determined in dependence on the application (BAUA, 2022). Repairs to the components of the heat transfer system may only be conducted by personnel with appropriate technical training (DIN, 2015).

The operator of the heat transfer system shall ensure that (FM Global, 2022):

- any and all system leaks are corrected promptly, regardless of how small they may be, making corrections of a permanent nature (e.g., repacking valve stems, replacing leaky gaskets, etc.), as applicable
- any fluid spilled from a leak shall be cleaned up immediately.
- any pipe or equipment insulation that is discovered to be oil-soaked is promptly removed and replaced with clean, oil-free insulation, and the cause of the leak is corrected.
- any openings in pipes or equipment (e.g., maintenance holes, instrument ports, inspection ports, etc.), are on the same inspection and maintenance schedule as all system equipment, seals, flanges, and other known potential leak points.

Periodic sampling of Terphenyl, hydrogenated is necessary to control and evaluate the quality of the Terphenyl, hydrogenated installed in the heat transfer system, in order to avoid any loss of efficiency in the overall heat transfer performance of the system. This process is performed a minimum of once a year (DIN, 2015).

The sampling of Terphenyl, hydrogenated from the heat transfer system, through the special equipment designed for this purpose, may only be conducted by persons with appropriate technical training (DIN, 2015). Specific operating instructions for taking samples of Terphenyl, hydrogenated from the heat transfer system have to be developed by the system operator in order to avoid the emission of the substance.

4.3. Top-up

The top-up (or refill) process is part of the general maintenance process. During the top-up process a Terphenyl, hydrogenated volume is managed out of the heat transfer system and, therefore, it is a potential emission source of Terphenyl, hydrogenated. For this reason, special containment measures shall be taken for the performance of this process.

The top-up demand is driven by the degradation rate of Terphenyl, hydrogenated, which partially decompose at elevated temperature, and the separated low-boiling degradation products. For this reason, a periodical collection of the decomposition products and a consequent refill with new Terphenyl, hydrogenated is needed. It has to be noted that the top-up process is not related to emission of Terphenyl, hydrogenated into the environment but to thermal degradation of the HTF.

Refilling of Terphenyl, hydrogenated to the heat transfer system may only be conducted by persons with appropriate technical training (DIN, 2015). Specific operating instructions for this process have to be developed by the system operator in order to avoid the emission of the substance

The refilling operation shall be conducted in a way remarkably similar to the filling operation (see **Section 3** of this document), taking into account that the volume of Terphenyl, hydrogenated involved in this process will be much smaller than in the case of filling. This means that the equipment and the technical and organisational measures during refilling will be the same as during filling. However, some additional care is needed (e.g., avoid adding wet fluid into the hot system). These specificities shall be included in the operating instruction of this process.

The degradation products of Terphenyl, hydrogenated (mainly low boiling fractions) must be separated from the heat transfer system, e.g., by venting, condensation, and collection for disposal, or by incineration via the flare system.

5. Dismantling/Decommissioning & Waste

The processes of dismantling, decommissioning, waste disposal, and cleaning of the heat transfer system are out of the usual operational conditions of the installation. In these processes Terphenyl, hydrogenated and Terphenyl, hydrogenated containing materials are managed out of the heat transfer system. Therefore, these processes are potential emission sources of Terphenyl, hydrogenated and, for this reason, special containment measures shall be taken for their performance.

The disposed Terphenyl, hydrogenated and Terphenyl, hydrogenated containing materials come from diverse sources:

- Periodical collection of degradation/decomposition products
- Complete drain of the heat transfer system
- Sampling of Terphenyl, hydrogenated for periodic quality control
- Spills and leakages
- Dismantling of the heat transfer system

The degradation/decomposition products (mainly low boiling fractions) formed as breakdown products of Terphenyl, hydrogenated at elevated temperatures, must be separated from the system. They can be treated in two diverse ways:

- They are collected into a vent line, condensed, and sent to a dedicated collection vessel or drum. In this case, these degraded products are low boiling components, which may contain fractions of Terphenyl, hydrogenated, that are disposed of externally through an authorized external company.
- They are vented in closed loops to be internally incinerated (through the furnaces, steam boilers, flares, etc., installed in the sites). In this case they are internally disposed of.

In case of complete drain of the heat transfer system, the used Terphenyl, hydrogenated shall be collected (e.g., in drain tanks) prior to be sent to an external waste operator.

The Terphenyl, hydrogenated amounts generated during the sampling process are collected in little containers.

The spills and leakages of Terphenyl, hydrogenated shall be removed by using absorbent material, such as mats or loose media. Once any remaining fluid has been absorbed, this material is removed for appropriate disposal.

In case a heat transfer system plant has to be dismantled, the whole heat-transfer system needs to be emptied, flushed, rinsed, and cleaned prior to dismantling. The solvent-water mixture containing Terphenyl, hydrogenated is disposed of through an external waste operator.

The technical measures introduced during the design and construction stages, together with the organisational measures, aim at fully enclosing the system and avoiding emissions to the environment during dismantling/decommissioning and disposal processes. Specific operating instructions for these processes have to be developed by the system operator in order to avoid the emission of the substance.

All of the above-mentioned materials (water fraction/emulsion with Terphenyl, hydrogenated, drained and sampled Terphenyl, hydrogenated, absorbent materials, water fraction/emulsion with Terphenyl, hydrogenated, and solvent-water mixture containing Terphenyl, hydrogenated) must be disposed in accordance with legislation applicable to waste oil (VDI, 1995). The aim is to recycle waste oil containing Terphenyl, hydrogenated in form of new materials or as energy (by burning in an authorized incinerator).

The owner of the waste oil is responsible by law for ensuring that its disposal is in accordance with the pertinent legislation. He may release the waste oil only to those refuse collectors who have been officially authorized for the purpose and must ensure that they hold a license for its collection and transportation (VDI, 1995).

The disposed products are transported directly inside the collection tanks, after drumming into barrels, or by truck. Piping and hoses of the trucks, collection tanks, and barrels are cleaned in the same disposal companies and the solvent-water mixture is disposed together with the received product.

It must also be ensured that the vehicles used for transport meet the requirements laid down in the regulations on transportation of dangerous goods by road (VDI, 1995).

Once a charge of Terphenyl, hydrogenated has been approved for disposal, it would be expedient to have it removed direct from the heat transfer system. If intermediate storage is necessary for logistic reasons, all the relevant legal provisions must be observed. This storage can be performed in tanks that conform to regulations on public transport (trucks tank) if the duration of storage is shorter than 24 hours or less, or until the next working day (VDI, 1995).

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6. Inspections & Training

In addition to the purely constructive and design measures, technical combined with organizational measures can also lead to a permanently technically tight plant. Apart from the human and technological factors, the organizational structure for safety measures also plays a key role when it comes to plant safety. The following elements needs integration into an appropriate organizational structure:

- responsibility;
- actions;
- procedures;
- processes;
- resources.

Such organizational structures are required to promote the high quality in terms of establishment, operation, change, maintenance, monitoring, emergency planning, accident prevention and limiting the negative effects of accident.

Inspections and training play a vital role in the organisational measures for plant safety.

6.1. Inspections

Heat transfer systems with organic heat transfer fluids are in general plants which require special supervision, including monitoring. From a legal point of view, they are "working equipment" and are therefore subject to the local safety regulations (HDI, 2016).

According to PED, most of the heat transfer systems with organic HTFs are requiring external inspections by third party accredited inspectors prior to commissioning and during operations. In the following, only the internal inspections (self-inspections) conducted by the trained and instructed site personnel are outlined.

The top priority of any inspection is to assist in eliminating or significantly reduce the risk of releases of Terphenyl, hydrogenated from any HTF plant into the environment. Inspections allow to see whether relevant regulations, standards and practices are being met, whether safety management systems are in place and function appropriately (with respect to technical, organisational, and human factor issues), and whether safety documentation is valid. The aim of the periodic inspection is to provide a statement that the system is in proper condition and that there are no safety concerns about the continued operation of the system against the continued operation of the system.

In general, all system parts which are relevant for the tightness of the plant, including valves, pumps, trace heating, electric equipment and special equipment are subject to obligatory regular inspections. The type, scope and frequency of inspections can be taken from the plant permit, legal and authority regulations, from technical rules and the operating instructions and manuals of the manufacturers of the system parts (HDI, 2016).

The entire system must be visually inspected by an instructed worker at regular intervals, but at least once a week. During system operation, hints pointing to defects shall always be observed, like (HDI, 2016):

- liquid pools or traces of HTF,

- accumulated incrustations,
- deformations,
- discolourations,
- unusual noises and smells,
- unusual smoke colours and
- smoke or vapour escaping from component joints or vents.

However, some workplaces might have higher risk areas that need to be inspected on a more frequent basis. The inspection strategy needs to be worked out depending on the level of risk.

The primary objective of the inspection is to identify potential causative factors for releases or potential releases of Terphenyl, hydrogenated into the environment. This would include the following:

- Infrastructure components such as surface sealing, loading docks, storage areas dewatering and drainage;
- HTF system parts such as piping, valves, pumps, trace heating, flanges;
- Handling and storage of materials in and around the workplace;
- Worker's behaviour;
- Faulty procedures that are ineffective or can cause releases;
- Newly introduced procedures and processes (MoC);
- Previously identified hazards that have not been addressed.

By maintaining a detailed record (see attached "Inspection Checklist"), the inspection can be documented and identified observations and deficiencies recorded and addressed. The inspection results shall contain the following information:

- Sections of the HTF plant that were inspected;
- System parts that were inspected;
- Processes that were inspected, e.g., top-up or refilling procedure;
- Time and date of inspection;
- Participating members of the inspection;
- Areas, processes, machinery, and other items that were found to be of potential risk for Terphenyl, hydrogenated release;
- Recommendations to address the issues.

Based on the site-specific conditions, the permits, the local regulations, applicable technical rules and the operating instructions and manuals of the manufacturers of the system parts, a plant specific inspection plan, including internal and external inspections, has to be compiled and kept up to date. **Table 1** is showing an example of an inspection plan template.

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Table 1: Example of an inspection plan template.

Type of Inspection	Frequency	Inspection by	March 2023
Top-Up Procedure	when occurring	Maintenance	
Sampling Procedure	annually	Laboratory	
Piping, Valves, Pumps	weekly	Maintenance	
Terphenyl, hydrogenated Waste Storage	monthly	EHS	
....	....	....	
....	....	....	
....	....	....	

6.2. Training

Under the REACH Restriction of Terphenyl, hydrogenated, the primary duty for the Terphenyl, hydrogenated downstream user in a HTF plant is to ensure that the substance is not released into the environment.

Organisational measures cannot substitute design and control engineering safety devices but are absolutely necessary in order to maintain the safety of a heat transfer oil system permanently, e.g., by correct operation (incl. training) and suitable maintenance. Thus, organisational measures are a complementary module for plant and process safety.

When instructing the workers, the employer shall take the necessary precautions to ensure that employees are provided with adequate information, in particular on the hazards arising from the work equipment in their immediate working environment, even if they do not use the equipment themselves. Where necessary, operating and work instructions for the equipment used at work have to be supplied in a form and language they can understand. During instruction, the employer must take the necessary precautions to ensure that (BG RCI, 2022):

- the workers who use the work equipment receive appropriate instructions in particular about the hazards associated with the use of the equipment;
- those responsible for conducting repair, maintenance, conversion, cleaning, and other work, receive appropriate special instruction.

The contents of the instruction must be adequate and recorded. Participants confirm by signature their participation in the instruction (BG RCI, 2022). In general, workers must (to the best of their ability) support all measures to prevent hazards and to follow the relevant instructions of the employer. They must use the equipment provided and must not follow instructions that are contrary to safety requirements.

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There are inherent dangers and complexities within chemical and process facilities, so companies must verify that employees have the knowledge to perform their duties safely and efficiently. Chemical safety training for operators, maintenance workers, EHS and inspection teams is intended to ensure that chemical facilities have trained workers needed to handle the chemicals and processes they manage and that they are knowledgeable about the chemical processes involved. Chemical safety training has therefore many benefits. It improves knowledge and adherence to safer practices, reduces exposure to chemicals and is essential for protecting human health and the environment and to ensure safety from potential hazards posed by chemicals, in manufacturing or other industries.

The **training needs** of such personnel and the provision of the suitable training has to be identified via a worker's specific analysis.

This could be relevant for subcontracted personnel working in the facility too. Therefore, appropriate measures shall be taken by the employer to ensure that workers in the Terphenyl, hydrogenated HTF plant receive sufficient and appropriate training and to raise awareness, in particular in the form of information and instructions, concerning:

- Potential risks of Terphenyl, hydrogenated exposure and environmental releases;
- Precautions to be taken to prevent exposure and incidents, incl. waste handling;
- Steps to be taken in case of spills and incidents;
- Process safety requirements and tasks to adequately control the risks.

The personnel managing the HTF plant and the Terphenyl, hydrogenated (e.g., in top-up and disposal) have to be appropriately trained and supervised. Training and supervision shall be a documented part of a systematic programme (not an isolated event). The identified training needs shall be documented by the site operator in a workers and plant specific training plan.

A training plan is the working document that contains information regarding how, when and where training has to be conducted. It also spells out the core details of a training program including its goals and objectives, duration, and assessment methods for certification. Having a training plan is important for an efficient training process and acts as a roadmap for instructions, sets realistic expectations for participants and keeps the instructor accountable. The employer shall document the successful completion of the training, which shall be renewed at least every five years. **Table 2** is illustrating an example of workers specific training plan template.

Table 2: Example of a workers specific training plan template.

Employee Name: John Schmitt Department: Maintenance Role: Maintenance Engineer					
Training Topic	Mode of Training	Training Hours	Expected Completion Date	Status	Recurring Training
Hazard Training on Terphenyl, hydrogenated used as the HTF	Online	4	Q4, 2022	completed	No
Spill & Emergency Procedures	Classroom	2	Q1, 2023	in progress	Yes
General System & Process Safety	Classroom	6	Q2, 2023	not started	Yes
Waste Management of Terphenyl, hydrogenated containing Waste	Classroom	4	Q1,2023	In progress	Yes
…………………	…………….	…………….	…………….	…………….	…………….

The training shall be:

- adapted to take account of new or changed risks;
- repeated periodically to relevant workers;
- documented to demonstrate that workers have successfully completed the training prior to working in the plant;
- conducted by a competent trainer/expert.

Training elements included, but not limited to, are:

- Hazard Training on Terphenyl, hydrogenated;
- general system & process safety;
- cleaning, leakages, maintenance, sampling;
- waste management of Terphenyl, hydrogenated containing waste;
- identification of critical handling stages;
- behaviour-based safety;
- management of change (MoC);
- evaluation of existing safety and working instructions.

The training shall comply with the provisions set by the Member State in which the industrial or professional user(s) operate. Member States may implement or continue to apply their own national requirements, as long as the above-mentioned minimum requirements are met.

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The restriction of isocyanates[142] (ECHA, 2020) can serve as a good reference, where new minimum training requirements[143] for workers which are managing diisocyanates and mixtures containing diisocyanates were introduced[144].

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[142] Registry of restriction intentions until outcome - ECHA (europa.eu)
[143] 503ac424-3bcb-137b-9247-09e41eb6dd5a (europa.eu)
[144] The EU introduces mandatory training of diisocyanates workers in new REACH Restriction - FSK - Fachverband Schaumkunststoffe und Polyurethane e.V. (fsk-vsv.de)

Annex 1: Inspection Checklist Template

Inspection Check List for Heat Transfer Systems designed to achieve the SCCS Condition

Requirements	**Response**		**Remarks**
	OK	**Action required**	
A. Installation and equipment			
Is the whole heat transfer system installed on a concrete (or equivalent) surface?			
Is the area under the heat transfer system designed to divert potential leakage and runoff to a safe location?			
Suitable equipment has been installed for this purpose (sloped floors, curbs, dikes, drainage systems, etc.)?			
Is potential leakage and runoff diverted to a closed containment system?			
Is potential leakage and runoff diverted to a waste treatment facility?			
Are vessels and tanks equipped with vents and/or expansion lines?			
Are vents and/or expansion lines routed into collection systems?			
Are vents and/or expansion lines connected to air pollution control equipment?			
Does the installation have calamity basin/tanks to control large accidental spills of Terphenyl, hydrogenated?			
Has the number of flanges in the piping lines been minimized to minimum technical requirements?			
Are there stop valves installed in the flow and return pipes?			
Has the suitability of the stop valves been proved (by manufacturer tests or an accredited expert)?			
Are the installed pumps prepared to contain leakages by themselves (magnetically driven, canned motor, double seals, liquid barrier, etc.)?			
If not, is it guaranteed that any leakage from the pumps will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Have the pump housings designed to withstand at least a maximum pressure of 16 bar?			
Has the suitability of the shaft seals been proved (by manufacturer tests or an accredited expert)?			
Is thermal insulation installed in such a way that leaks can be detected?			
Is the equipment for sampling points of Terphenyl, hydrogenated specially designed to contain leakages?			
Are all the other installed components (valves, flanges, seals, connections, etc.) prepared to contain leakages by themselves?			
If not, is it guaranteed that any leakage from them will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Are there control equipment and safety devices in place to ensure the safety of the system and the process?			

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Requirements	**Response**		**Remarks**
	OK	**Action Required**	
B. Filling, start-up, shutdown, and drain of Terphenyl, hydrogenated			
Has the heat transfer system been provided with accessories to ensure the safe performance of these operations?			
Have start-ups and shutdowns been minimized according to the site-specific operations?			
Please, provide the number of start-ups and shutdowns from the last inspection.			
Are there operating instructions for start-up and shutdown?			
Are start-up and shutdown performed by qualified persons?			
Has the Terphenyl, hydrogenated completely drained (due to degradation) and filled from the last inspection?			
If so, were all the components (pumps, piping, connections, etc.) of the heat transfer system continuously monitored for leakages during these operations?			
Are there operating instructions for the complete drain and filling of Terphenyl, hydrogenated?			
Is the complete drain and filling of Terphenyl, hydrogenated performed by qualified persons?			
C. Operation of the heat transfer system			
Has an operating limit for pressure been established?			
Has any deviation from the pressure limit been detected since the last inspection?			
If yes, please specify how many pressure limit deviations have been detected and which values were reached.			
Has an operating limit for temperature been established?			
Has any deviation from the temperature limit been detected since the last inspection?			
If yes, please specify how many temperature limit deviations have been detected and which values were reached.			
Has an operating limit for Terphenyl, hydrogenated level been established?			
Has any deviation from the Terphenyl, hydrogenated level limit been detected since the last inspection?			
If yes, please specify how many Terphenyl, hydrogenated level limit deviations have been detected and which values were reached.			
Has an operating limit for flow rate been established?			
Has any deviation from the flow rate limit been detected since the last inspection?			
If yes, please specify how many flow rate limit deviations have been detected and which values were reached.			
Is there an operating manual for the heat transfer system?			
Are there operating instructions for the heat transfer system?			
Are there operating instructions for handling Terphenyl, hydrogenated?			
Are operating manual and operating instructions always available to the workers in a form and language they can understand?			

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Requirements	**Response**		**Remarks**
	OK	**Action Required**	
D. Maintenance of the heat transfer system			
Is there a preventive maintenance plan in place?			
Are there operating instructions for maintenance and repair work?			
Is maintenance performed by qualified persons?			
Are control and safety devices checked for their effectiveness?			
Are all the openings in the installation (e.g., maintenance holes, instrument ports, etc.) included in the maintenance plan?			
Is the heat transfer system or parts of it tested for leakage detection?			
How is the heat transfer system or parts of it tested for leakage detection? Which tests are conducted (e.g., use of foaming agents, acoustic test, etc.)?			
Installation area			
Heater			
Vessels and tanks			
Vents and relief devices			
Piping and piping parts			
Pumps			
Thermal insulation			
Sampling points			
Valves			
Flanges			
Seals			
Connections			
Control equipment			
Safety devices			
Is the heat transfer system or parts of it checked visually during operation for leakage detection?			
Are these tests performed according to the procedures defined by the manufacturer or other accepted standards?			
If so, which ones are used?			
What are the time intervals of the tests for leakage detection?			
Is there a test book or written records about these tests?			
Is the heat transfer system or parts of it tested for leakage detection before the start-up, during the filling and drain of Terphenyl, hydrogenated, and after the shutdown of the operation?			
Is the heat transfer system or parts of it checked visually during these activities to detect leakages?			
Is the painting with wetting agents test (e.g., soap solution) performed during these activities to detect leakages?			
Is thermal insulation removed during these activities to facilitate the detection of leakages?			
Is the plant or parts of the plant tested for leakage detection after adaptations, maintenance, and repair?			
Are there operating instructions for the detection of leakages?			
Requirements	**Response**		**Remarks**
	OK	**Action Required**	
E. Maintenance of the heat transfer system (cont.)			

Are tests for leakage detection performed by qualified persons?			
Are leakages corrected promptly (regardless of how small they may be)?			
Are the leakages corrections of a permanent nature?			
Are leakages cleaned up immediately?			
Are there operating instructions for the elimination and cleaning of leakages?			
Is the elimination and cleaning of leakages performed by qualified persons?			
Is the oil-soaked thermal insulation promptly replaced and the cause of the leak corrected?			
Is Terphenyl, hydrogenated sampled and its quality controlled a minimum of once a year?			
Are there operating instructions for sampling of Terphenyl, hydrogenated?			
Is Terphenyl, hydrogenated sampling performed by qualified persons?			
Are there operating instructions for top-up of Terphenyl, hydrogenated?			
Is top-up of Terphenyl, hydrogenated performed by qualified persons?			
F. Dismantling/decommissioning and waste disposal			
How are the low boiling fractions disposed of?			
Vented, condensed, collected, and externally disposed of.			
Vented and internally incinerated.			
Is the drained Terphenyl, hydrogenated from the heat transfer fluid collected (vessels/tanks)?			
Is the sampled Terphenyl, hydrogenated collected (little containers)?			
Are spills removed using absorbent material?			
Has the heat transfer system or parts of it been dismantled after the last inspection?			
If so, was the heat transfer system emptied, flushed, rinsed, and cleaned prior to dismantling?			
Are the above-mentioned materials disposed of internally?			
If so, is the company officially authorized, holding a license for waste collection?			
Are the above-mentioned materials recycled as energy by internal incineration?			
Are the above-mentioned materials disposed of by external companies?			
If so, are these external companies officially authorized, holding a license for waste collection and transportation?			
Do the vehicles used for transportation meet the requirements laid down in ADR?			
Are the above-mentioned materials recycled as energy by authorized external incinerators?			
Is intermediate waste storage necessary?			
If so, are all the relevant legal provisions observed?			
Are there operating instructions for dismantling and waste disposal?			
Are dismantling and waste disposal performed by qualified persons?			

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Requirements	**Response**		**Remarks**
	OK	**Action Required**	
G. Training			
Is there a general training plan in place?			
Are there specific training plans per job position/activity?			
Are the training needs of each job position evaluated and documented?			
Does the content of each specific training include adequate information about the hazards associated with the use of Terphenyl, hydrogenated?			
Does the content of each specific training include adequate information about the hazards associated with the use of the equipment?			
Does the content of each specific training include adequate information to avoid the release of Terphenyl, hydrogenated into the environment?			
Does each specific training comply with the provisions set by all the Legislation applicable to the job position/activity?			
Are the contents of each specific training recorded?			
Do the participants confirm by signature their participation in each specific training?			
Is the completion of each specific training documented?			
Is the effectiveness of each specific training evaluated?			
Has the periodicity of each specific training been defined?			
Has the training level of the subcontractors been evaluated?			
H. Inspection			
Has an inspection plan been defined for the heat transfer system?			
Are external inspections by third-party accredited inspectors required prior to start-up of the heat transfer system or parts of it?			
Are external inspections by third-party accredited inspectors required during operation of the heat transfer system or parts of it?			
If so, how often are these inspections conducted?			
Are internal inspections by trained and instructed site personnel performed on the heat transfer system or parts of it?			
If so, how often are these inspections conducted?			
Are the results of these inspections documented?			
Are the identified observations and deficiencies recorded and addressed?			
Result of the inspection			
After this inspection, can be considered the heat transfer system permanently technically tight (system achieving SCCS condition)?			
Members of the inspection team			
Date of the inspection			

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References

BAUA 2022. TRGS 722. Technical Rules for Hazardous Substances, Avoidance or Minimizing dangerous explosive mixtures. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAUA), 2022

BG RCI, 2022. Safety considerations when operating heat transfer plants with organic heat transfer media. German Social Accident Insurance Institution for Chemical Industry (BG RCI). Last consulted: November 2022

COM 2007. Reference Document on Best Available Techniques (BREF) in the Production of Polymers. European Commission, August 2007.

DIN 2015. DIN 4754-1 Heat transfer installations working with organic heat transfer fluids – Part 1: Safety requirements, test. DIN, 2015

ECHA 2020. Annex XVII to REACH – Conditions of restriction – Entry 74 - Diisocyanates, O = C=N-R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length. European Chemicals Agency (ECHA), August 2020

ECHA 2019. How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl-2-pyrrolidone). European Chemicals Agency (ECHA), July 2019

ECHA 2014. How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID. Practical Guide 16. European Chemicals Agency (ECHA), June 2014.

ECHA 2010. Guidance on intermediates. Version 2. European Chemicals Agency (ECHA), December 2010

FM Global 2022. Property Loss Prevention Data Sheets 7-99 Heat Transfer fluid systems. FM Global 2022

GAP 2013. Guidelines Organic & Synthetic Heat Transfer Fluids and Equipment. Global Asset Protection Services, 2013

HDI 2016. Risk Engineering Guideline – Heat Transfer Oil Systems. HDI Risk Consulting GmbH, 2016

VDI, 1995. VDI 3033. Heat transfer systems with organic heat transfer media – Operation, Maintenance, and repair. Verein Deutscher Ingenieure e.V. (VDI), 1995

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