5 March 2020

Draft background document for terphenyl, hydrogenated

Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of terphenyl, hydrogenated on the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 5 June) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: Terphenyl, hydrogenated
EC Number: 262-967-7
CAS Number: 61788-32-7

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[2]. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation are available at https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

2.1. Intrinsic properties

Terphenyl, hydrogenated was identified as a Substance of Very High Concern (SVHC) according to Article 57(e) as it meets the criteria of a vPvB substance and was included in the Candidate List for authorisation on 27/06/2018, following ECHA's decision ED/61/2018.

2.2. Volume used in the scope of authorisation

The amount of terphenyl, hydrogenated manufactured and/or imported into the EU is according to registration data (ECHA, 2019) in the range of 1,000 - 10,000 t/y. Part of this tonnage is exported outside the EU. All the uses appear to fall within the scope of authorisation, except some uses in scientific research and development, to the extent they fall under the generic exemption from authorisation requirement. Taking into account the information available on the tonnage corresponding to those uses, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of terphenyl, hydrogenated in the scope of authorisation include uses at industrial sites (use in heat transfer fluids, use as solvent/process medium, formulation and use of adhesives and sealants, paints, coatings, inks, formulation and use of additives in plastics as well as formulation of construction products) and uses by professional workers (uses of adhesives and sealants, coatings/inks and paints).

Furthermore, according to registrations the substance is used in articles in volumes above 10 t/y (e.g. plastic articles).

More detailed information on uses is provided in Annex I.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Terphenyl, hydrogenated is identified as vPvB meeting the criteria of Article 57 (e) Score: 13	The amount of terphenyl, hydrogenated used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	Terphenyl, hydrogenated is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 12	37

Conclusion

On the basis of the prioritisation criteria, terphenyl, hydrogenated receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise terphenyl, hydrogenated for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[3] and the criteria described in the implementation document[4]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the “later” LAD slots.

A summary of the information currently available is provided in Annex I.

[3] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf

[4] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 10th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for terphenyl, hydrogenated.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of terphenyl, hydrogenated on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU

legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[5]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[6], there is no need to propose an additional specific exemption.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of terphenyl, hydrogenated for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for terphenyl, hydrogenated[7].

[5] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[6] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf

[7] As of 15 September 2019

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Terphenyl, hydrogenated. Submitted by Finland, February 2018.

https://echa.europa.eu/documents/10162/3c36efa2-f86b-5065-1fbe-eb60459b4806

ECHA (2019): Terphenyl, hydrogenated. ECHA's dissemination website on registered substances. Accessed on 15 September 2019.

https://echa.europa.eu/search-for-chemicals

RCOM (2018): "*Responses to comments*" document. Document compiled by Finland from the commenting period 8/03/2018 - 23/04/2018 on the proposal to identify Terphenyl, hydrogenated as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e18250183f

Annex I: Further information on uses

1. Information on uses

Registered uses of terphenyl, hydrogenated includes formulation and uses at industrial sites, uses by professional workers, and uses in articles.

Consumer uses (as additive is sealant and adhesive applications, in plastic applications and in coatings, paints and inks) were previously reported in registrations dossiers but are not supported anymore in the current active registrations (ECHA, 2019). Some registrants report the consumer uses in coatings, inks, adhesives and sealants as uses advised against.

During the SVHC consultation (RCOM, 2018), comment submitters have provided some additional information on active uses (see below). No comments on the uses in coatings, inks and paints have been received.

- **Use as Heat transfer fluid**

One of the major registrants indicated that terphenyl, hydrogenated is a significant commercial product in Europe, manufactured by the company under the name Therminol™ 66 and used predominantly as a heat transfer fluid (HTF) in high temperature, non-pressurised closed manufacturing systems, including those for polymers, waste heat recovery, oil and gas, petrochemicals, and renewable energy (RCOM, 2018). The comment submitter further noted that as an ingredients in heat transfer fluids, terphenyl, hydrogenated is critical to many industrial processes, including, among others, the manufacture of polyethylene terephthalate (PET) and the conversion of biomass to energy.

The company itself is a direct user of the substance in two of its plants where petrochemicals, basic chemicals, or resins products are produced. Several individual companies from various sectors commented on the use of terphenyl, hydrogenated for its properties as heat transfer fluid. Some provided estimations on the number of installations where the substance is used. One company indicated that to its knowledge there are more than 400 systems installed in Germany and Austria, relying on terphenyl, hydrogenated in thermal oils products. Another one estimated the number of users in Italy to be above 400 (RCOM, 2018).

- **Plasticizer in plastics, adhesives and sealants applications**

One of the major registrants indicated that the substance is used as a plasticiser in high-voltage underground cables, aircraft sealants and other plasticiser applications.

Downstream sectors (Gifas[8] and the Aerospace Industries Association) confirmed the use of the substance in their sector in sealants. The Aerospace Industries Association further specified that the substance 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. Polysulfide sealants are broadly used in the aerospace and defense industry because they provide flexible and chemically resistant sealing with low moisture permeability. Other uses of the substance in polysulfides includes specialty aerospace sealants for fuel tanks, window installations, sealing sandwich assemblies, self-leveling compounds, hole filling, low density, fast cure sealants, temperature-resistance, fuel, pressure and weather resistance, and

[8] Groupement des industries françaises aéronautiques et spatiales

pressure and environmental sealants. They are also used in potting compounds for potting of electrical connectors and potting inserts in sandwich panels.

The Aerospace Industries Association indicated that the substance can also be used in structural adhesives (terphenyl is used in the catalyst component of general purpose epoxy adhesives used to bond metals, printed circuit boards, electronic components, glass and plastics) and in other processes (hydrogenated terphenyls are also found in tapes, electrical insulating coating compounds, epoxies, polyurethane potting and molding compounds, and electric cables).

One individual company commented on its use of terphenyl hydrogenated as ingredient in formulation of a bitumen based polyurethane used for expansion joints in concrete constructions and filling compound for underground high voltage joints up to 550 kV.

2. Market trend and possible alternatives

No information on the market trend of terphenyl, hydrogenated is available in registration dossiers and such information has not been provided during SVHC consultation.

It is noted that two substances having structural similarities and common uses with terphenyl, hydrogenated are currently under scrutiny by Finnish Authorities in the context of an RMOA[9]. The ongoing RMOA activity covers two substances (dibenzylbenzene, ar-methyl derivate (EC 258-649-2) and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (EC 400-370-7)) and is motivated by a functional grouping approach for high temperature, non-pressurised heat transfer fluids that might be used as substitutes for terphenyl, hydrogenated[10].

3. Structure and complexity of supply chains

The following assumptions are made on the structure and complexity of supply chains based on currently available information. This will be used, together with any relevant information from consultation, to allocate the substance to a specific LAD slot in the final recommendation.

Terphenyl, hydrogenated is manufactured and/or imported by a limited number of registrants. No precise and up-to-date information is available on the total number of industrial sites where the substances is currently used. However, based on the information available, this number is expected to be well above 100.

The supply chain can be characterised[11] by the following actors: formulators, users at industrial sites (including articles producers), professional workers and users of articles (relevant life cycle stages: F, IS, PW, SL).

Terphenyl, hydrogenated seems to be used in the following product types: adhesives, sealants, coatings, inks, paints, heat transfer fluids, polymer preparations and process medium products (Relevant product categories: PC1, PC9a, PC9b, PC16, PC32, PC0/PC20)[12].

[9] **R**egulatory **M**anagement **O**ption **A**nalysis: https://echa.europa.eu/understandng-rmoa
[10] Further information on the ongoing RMOA can be found at https://echa.europa.eu/rmoa/-/dislist/details/0b0236e1834a0ed6
[11] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf
[12] The substance is also reported for use as laboratory chemical (PC21). This use/product type is not reflected here as it might fall outside the scope of authorisation and therefore not contribute to the workload at Afa stage.

Various sectors are relying on the substance in some of their uses including: manufacturers of fine chemicals, bulk/large scale chemicals, plastic products, electrical equipment, transport equipment as well as the construction and electricity/steam/gas/water supply sectors (relevant sector of use categories: SU8, SU9, SU12, SU16, SU17, SU19, SU23).

Uses of terphenyl, hydrogenated in the scope of authorisation seem to be relevant for the production of a number of article types such as plastic articles and electrical/electronic articles (e.g. thermostats) (relevant article categories: AC2, AC13).

Some of the categories mentioned above are not explicitly reported in registrations but could be derived from other information on uses available in registration dossiers, from information from substance in article notifications and from information submitted during consultation (RCOM, 2018).