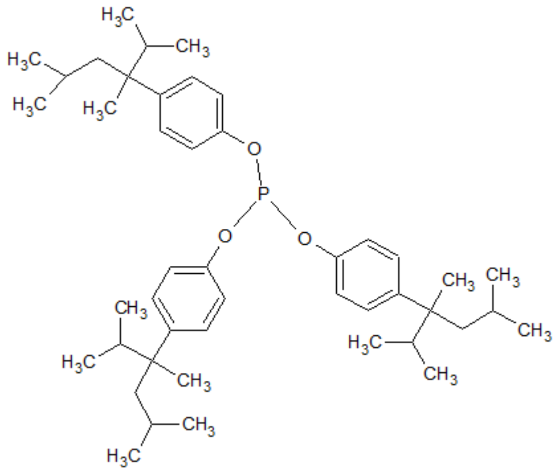
SUBSTANCE EVALUATION CONCLUSION and EVALUATION REPORT

for

tris(4-nonylphenyl, branched) phosphite

List No 701-028-2

Formerly identified as tris (nonylphenol) phosphite,
EC number: 247-759-6, CAS RN: 26523-78-4



Evaluating Member State Competent Authority: France

Dated: 16 July 2024

Evaluating Member State Competent Authority

MSCA name:	French Agency for Food, Environmental and Occupational Health Safety (ANSES) on behalf of the French Ministry of Ecological Transition
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Year of evaluation in CoRAP: 2013

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Further information on the substance evaluation process here:

https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

DISCLAIMER

Foreword

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the outcome of the Substance Evaluation carried out by the evaluating MSCA. The document consists of two parts i.e. A) the conclusion and B) the evaluation report.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the Substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating MSCA. In case the evaluating MSCA proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating MSCA, it does not preclude other MSCAs or the European Commission from initiating regulatory risk management measures which they deem appropriate.

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Part A. Conclusion

In the conclusion (part A), the evaluating MSCA considers how the information on the Substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. Alternatively, the outcome of the evaluation may be that presently there is no need for regulatory follow-up at EU level if sufficient information on the potential hazards is available and all necessary measures for safe handling of the substance are in place.

1. Scope of the evaluation

tris(4-nonylphenyl, branched) phosphite ("the Substance") was originally selected for substance evaluation to clarify concerns about:

- PBT/vPvB
- Consumer use
- Exposure of sensitive populations
- High (aggregated) tonnages
- High RCR
- Wide dispersive use

During the evaluation, the following additional concern was identified:

- Endocrine disruption (environment)

2. Overview of other processes / EU legislation

Table 2-1 Overview of other processes / EU legislation

No other processes	CCH	TPE	GMT	Previously on CoRAP	Annex VI (CLP)	Annex XVII (Restriction)	Candidate List/Annex XIV (Authorisation)
☐	☒	☐	☒	☒	☒	☐	☒

Other EU legislation	Previous legislation	Stockholm convention	Other
PPP/BPR	NONS/RAR	POP	(e.g., UNEP)
☐	☒	☐	☐

Other EU legislation

The Substance was included in the list of hazardous substances of the following EU directives:

- Directive 90/385/EEC on active implantable medical devices, particularly as regards Article 3 and Annex I (Essential Requirements). Regulation (EU) 2017/745 on medical devices has repealed Directive 90/385/EEC and begun to apply from 26 May 2021.
- EU Hazardous Substances for Purposes of Annex I (3) (Requirements for Construction Works), Regulation 305/2011/EU on Marketing of Construction Products, amended by Regulation 574/2014/EU, 28 May 2014.
- EU Ecolabel Regulation, the ecolabel must not be awarded to goods containing substances or mixtures classified according to the CLP as toxic; hazardous to the environment; and carcinogenic, mutagenic, or toxic for reproduction (CMRs). Nor are products allowed the ecolabel award when they contain SVHCs (per Article 57 of REACH).
- EU. Hazardous Substances for Purposes of Directive 2008/56/EC (Marine Strategy Framework Directive), 25 June 2008, amended by Directive 2017/845/EU, 18 May 2017

3. Conclusion and regulatory follow-up action

The evaluation of the available information on the Substance has led the evaluating MSCA to the following conclusions.

Table 3-1 Conclusion and regulatory follow-up action

Initial and additional concern	**Conclusion on concern**	**Regulatory follow-up action**
PBT/vPvB	Inconclusive As explained in section 16 (PBT/vPvB assessment), the evaluating MSCA considers that no further actions are required at this stage for PBT/vPvB properties. However, the potential PBT/vPvB properties of the Substance could be further investigated via a compliance check (CCh).	No need for regulatory follow-up at EU level
Endocrine disruption (environment)	Concern confirmed The Substance is considered as an endocrine disruptor due to the formation of 4-nonylphenol branched as degradation/transformation product of the Substance. Following SVHC identification as an endocrine disruptor for the environment and pending final provisions in CLP revision, the Substance would consequently be classified as ED ENV in Category 1 with the hazard statement: May cause endocrine disruption in the environment, under CLP regulation.	Identification as SVHC (authorisation) Harmonised classification and labelling
Consumer use	Concern confirmed Some registrants notify in their registration dossiers consumer use due to food contact polymer articles and in adhesives and sealants, coating products and polymers.	
Exposure of sensitive populations	Concern confirmed Since some registrants notify in their registration dossier widespread uses of professionals, consumers and subsequently in article service life, exposure of sensitive populations is therefore expected.	
High (aggregated) tonnages	Concern confirmed	
High RCR	Inconclusive	
Wide dispersive use	Concern confirmed Considering that potential release to the environment can occur from widespread uses of professionals, consumers and subsequently in article service life. Wide dispersive uses are likely.	

4. Regulatory follow-up actions at EU level

4.1 Harmonised Classification and Labelling

Considering the criteria of new hazard classes under CLP regulation[1], following the SVHC identification of the Substance under REACH article 57f due to their endocrine disruptor properties for the environment, the Substance should consequently be classified as ED ENV in Category 1 with the hazard statement: May cause endocrine disruption in the environment, under CLP regulation.

In addition, as explained in section 7, the identity of tris(nonylphenyl) phosphite was clarified during the Substance evaluation. Consequently, the previous EC number (EC No 247-759-6) was replaced by a List number. Therefore, the existing harmonized classification does not currently apply to the Substance as listed in Annex VI of CLP because of the change in identifiers. Modification of the substance identifiers associated to the harmonised classification should be performed.

4.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Based on the presence of the impurity 4-nonylphenol branched, two grades of tris(4-nonylphenyl, branched) phosphite are notified:

- The high purity grade of tris(4-nonylphenyl, branched) phosphite, refers to the substance with less than 0.1% w/w of 4-nonylphenol branched as impurity.
- The 'commercial' grade refers to the presence of 4-nonylphenol branched at concentrations higher than or equal to 0.1% w/w of 4-nonylphenol as impurity.

4-Nonylphenol, branched was identified as an SVHC and included in the Candidate List (Decision ED/169/2012 of 18 December 2012) due to the endocrine disrupting properties which cause probable serious effects to the environment.

On July 2019, the 'commercial' grade tris(4-nonylphenyl, branched) phosphite with ≥ 0.1% w/w 4-nonylphenol branched was identified as an SVHC[2] based on the presence of 4-nonyl phenol branched ≥ 0.1% w/w as impurity.

Concerning the high purity grade of tris(4-nonylphenyl, branched) phosphite, the evaluating MSCA, based on a weight of evidence assessment approach of the overall information, considers that there are sufficient information to conclude that tris(4-nonylphenyl, branched) phosphite can degrade to 4-Nonylphenol, branched under relevant environmental conditions. Tris(4-nonylphenyl, branched) phosphite can be a source of 4-Nonylphenol, branched to the environment. Consequently, the Substance should be considered as endocrine disruptor for the environment.

Therefore, the evaluating MSCA concludes that the Substance in its high purity grade, which include also any of the individual isomers and/or combinations thereof, can be identified as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) due to their degradation to a substance of very high concern (4-Nonylphenol, branched). It gives rise to the same equivalent level of concern to those substances listed in point (f) of Article 57 of REACH Regulation.

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[1] COMMISSION DELEGATED REGULATION (EU) 2023/707 of 19 December 2022, amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification,
labelling and packaging of substances and mixtures
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707&from=EN

[2] Agreement of the Member State on the identification of TNPP in their commercial form as a substance of very high concern https://echa.europa.eu/fr/candidate-list-table/-/dislist/details/0b0236e1833efad1

SVHC identification will bring immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold. This proposal is in line with the strategy proposed in the analysis of risk management option (RMOA) carried out on tris(4-nonylphenyl, branched) phosphite and published[3] on October 8, 2018.

4.3 Restriction

Based on the confirmed ED properties for the environment of the Substance (also in its high purity grade) and consequently their identification as SVHC under Article 57 (f) of Regulation (EC) 1907/2006 (REACH), the need for a possible restriction could be further investigated.

The need for a possible restriction was proposed by ECHA in the frame of an Assessment of regulatory needs (ARN) for a group of "Triphenylphosphite and its derivates"[4] which include the Substance.

Wide dispersive uses by professionals and consumers as well as from article service life are notified in the registration dossiers of some registrants. Thus, releases to the environment are likely to occur. According to ECHA, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers, industrial workers, might be considered after SVHC identification to minimise exposure and emissions of the Substance to the environment. In the assessment of ECHA, it is also highlighted that assessment work of the regulatory needs of several groups of hydrocarbylphenols[5] are currently ongoing and the fact that other carbylphenol containing substances might have similar use profiles, ECHA considers that a wider restriction could be applicable on a larger group of substances for some specific uses that would mitigate the risk of regrettable substitution.

At this stage, the evaluating MSCA does not propose to undertake a restriction proposal for this Substance. This conclusion might be reconsidered after SVHC identification.

4.4 Other EU-wide regulatory risk management measures

Not applicable

5. Currently no need for regulatory follow-up at EU level

Not applicable

6. Tentative plan for follow-up actions

As indicated in Table 6-1, the following regulatory action(s) at EU level are proposed.

Table 6-1 Follow-up actions

Follow-up action	Date for intention	Actor
SVHC Identification (authorization)[6]	August 2024	France

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[3] RMO TNPP https://echa.europa.eu/fr/assessment-regulatory-needs/-/dislist/details/0b0236e1811f4fc7

[4] Assessment of regulatory needs "Triphenylphosphite and its derivates" https://echa.europa.eu/documents/10162/36ac283b-41f1-1019-2a0a-33b88990af20

[5] Assessment regulatory needs "Hydrocarbylphenol" https://echa.europa.eu/documents/10162/c7c4156f-9a11-df42-e754-124a5c264b68

[6] Following SVHC identification as an endocrine disruptor for the environment and pending final provisions in CLP revision, the Substance would consequently be classified as ED ENV in Category 1 with the hazard statement: May cause endocrine disruption in the environment, under CLP regulation.

Part B. Substance evaluation report

7. Overview of the Substance Evaluation Process

Tris(nonylphenyl) phosphite (CAS RN 26523-78-4 at that time) was first assessed under the Existing Substances Regulation (ESR, Council Regulation (EEC) No. 793/93). An Annex XV transitional report[7] and a risk assessment report[8] were prepared by France and published in 2008. Regarding human health, a concern of skin sensitisation upon dermal contact during the manufacture of the substance, manufacture of products containing Tris(nonylphenyl) phosphite and use of preparations containing Tris(nonylphenyl) phosphite was identified.

A Risk Reduction Strategy with respect to workers has been developed and agreed in April 2008. Classification of Tris(nonylphenyl) phosphite as a sensitizer was finalised in the Commission working group on the Classification and Labelling of Dangerous Substances in November 2005.

The environmental risk assessment was incomplete when the ESR work ceased. The RAR concluded to a need for further testing. The requirements reported in the Regulation EC n° 466/2008/EC (on certain priority "existing" substances) included:
- Information on structure of Tris(nonylphenyl) phosphite;
- Information on water solubility;
- Log Kow determination;
- Hydrolysis test;
- Toxicity test with daphnia magna chronic test provided for the classification.

Tris(nonylphenyl)phosphite (CAS RN 26523-78-4) has an harmonised classification and labelling (ATP03). The substance is classified as: very toxic to aquatic life, very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.

Most of the information requested in the Regulation EC n° 466/2008/EC was not provided and the initials concerns e.g. regarding impurities (nonylphenol), PBT/vPvB properties remained unsolved. The substance was included in the Community rolling plan (CoRAP) of REACH for substance evaluation in 2013 for the initial grounds of concern relating to Environment/Suspected PBT; Exposure/wide dispersive use; consumer use; Exposure to sensitive populations; high RCR; aggregated tonnage.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA evaluated the Substance based on the information in the registration dossier(s) and on other relevant and available information.

Tris(4-nonylphenyl, branched) phosphite was initially registered as a mono-constituent (formerly identified as tris (nonylphenol) phosphite, EC No 247-759-6, CAS RN 26523-78-4). However, during the substance evaluation process, ECHA has considered that the substance identity needed to be adapted for appropriately reflecting the identity and composition of the registered substance. Therefore, a decision was addressed to registrants requesting information to clarify the identity and composition of the Substance. The identity and composition were clarified, and the identification numbers were changed accordingly in March 2016.

During the Substance evaluation, an additional concern was identified regarding endocrine disruptor properties by:

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[7] https://echa.europa.eu/documents/10162/17228/trd_france_tnpp_en.pdf/bb9a1ece-0d7d-4fe3-8564-ffd667d08313

[8] https://echa.europa.eu/documents/10162/17228/trd_rar_env_france_tnpp_en.pdf/3c52a33e-5c4b-4640-b863-94198d406924

i) The presence of the impurity 4-nonyl phenol branched ≥0.1% in some commercial form of the Substance. 4-nonylphenol, branched is a Substance of Very High Concern (SVHC) based on its endocrine disruptor properties. Therefore, on July 2019, the Substance, in its commercial form containing as an impurity 4-nonyl phenol branched ≥ 0.1% w/w, was identified as a SVHC based on the presence of 4-nonyl phenol branched ≥ 0.1% w/w as impurity.

ii) The potential degradation of the Substance, even in its high purity grade, into 4-nonylphenol branched.

In order to clarify the formation of 4-nonylphenol branched through degradation of Tris(4-nonylphenyl, branched) phosphite, a decision SEV-D-2114516891-47-01/F[9] was addressed to Registrant(s) in September 2020, requesting a hydrolysis test (test method: EU c.7/OECD TG 111) with the detection of total branched 4-nonylphenol and, if needed, a simulation test on ultimate degradation in surface water (Aerobic mineralization in surface water – test method EU C.25/OECD TG 309). Because of the low solubility of Tris(4-nonylphenyl, branched) phosphite, it was recommended to carry out the test with silica gel as sorbing material to increase the dispersion of the test Substance. This method was successfully used in a hydrolysis test with triphenyl phosphite[10]

On 23 August 2022, the Registrant(s) updated the registration dossier including the robust study summary of the hydrolysis study and a justification for waiving the simulation study.

After examination of the information provided, the evaluating MSCA noted that the submitted information provides indications of formation of 4-nonylphenol branched but the study did not fulfill the requirements made in the original decision SEV-D-2114516891-47-01/F. Therefore, a draft decision in accordance with article 46(3), requesting the same information as the original decision, was notified to the registrant(s) for comments.

In their formal comments on the draft decision, the Registrant(s) indicated that the hydrolysis study provided in 2022 addressed the fundamental question of whether the Substance could form branched 4-nonylphenol (4-bNP) at ≥ 0.1% w/w. In the Registrant’s opinion, the results of the study show that the Substance forms 4-nonylphenol branched at ≥ 0.1% w/w. Subsequently, they considered that the question having been resolved following the results of the first study, a repetition of the hydrolysis study was not justified. Moreover, the registrant(s) reminded that repeating the study is challenging due to technical issues (low water solubility and adsorptive properties e.g. solubilisation and analytical monitoring difficulties).

Following the Registrant’s comments, the evaluating MSCA consulted the Member State Committee (MSC) during the 83rd MSC meeting[11] in order to share with them the assessment of the hydrolysis study, the technical issues associated on the test and the claim of the registrant(s) that “*the Substance forms branched 4-nonylphenol (4-bNP) at ≥ 0.1% w/w*”. The MSC considered that there may be sufficient information available to clarify degradation of the Substance to 4-nonylphenol, branched (4-bNP). Consequently, requesting further information related to this matter may not be necessary.

Taking into consideration the overall data, the registrant’s comments and conclusion of the MSC during the 83rd MSC meeting, the evaluating MSCA considers that the available information is sufficient to conclude on the hazard of the Substance.

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[9] Decision: https://echa.europa.eu/documents/10162/23645b9b-137c-c5f9-ac49-366e4d0af659

[10] https://echa.europa.eu/docume+nts/10162/fc02208b-9999-388f-440d-e25b7e03f591

[11] Public minutes of MSC-83 meeting: https://echa.europa.eu/documents/10162/18249823/minutes_msc-83_en.pdf/bec6c36b-cf7f-7ae2-8d19-898e769dd322?t=1697178582261

8. Substance identity

Tris(nonylphenyl)phosphite was initially registered as a mono-constituent. However, during the substance evaluation process, the identity and composition of the registered substance was clarified.

The information on tris-(4-nonylphenol branched)phosphite, including identifiers and structural formula, can be found on the cover page. For more details see ECHA: https://echa.europa.eu/home

Synonyms:

- Phenol, nonyl-, phosphite (3:1)
- tris (4-nonylphenol, branch) phosphorous acid ester
- tris (4-nonylphenyl, branched) phosphite

Trade names:

- ADK STAB 1178
- DOVERPHOS 4
- DOVERPHOS HIPURE 4
- Mark CH 55
- Markphos TNPP
- Nauguard TNPP
- Nauguard TNPP HR
- Rostabil TNF
- Rostabil TNF HR
- tris(nonylphenyl) phosphite
- TNPP

8.1. Type of Substance

Tris-(4-nonylphenol branched)phosphite is considered an UVCB according to Guidance for identification and naming of substances under REACH and CLP.

Each registrant provided analytical information (UV/VIS, IR, NMR and GC chromatograms) to confirm the compositions and the structure of its substance. According to manufacturing process, the starting material is a complex mixture of para-substituted phenol (EC No. 284-325-6, synonym: 4-nonylphenol, branched), which has a varied and complex branching on the nonyl chain. Therefore, the synthesis product leads to tris(4-nonylphenol, branched) phosphorous acid ester.

There are variations from one registrant to another concerning the specification of one impurity. In addition, one additional additive was present in one composition which is not consistent with the boundary composition. However, the presence of the additive has no consequence on classification. Please refer to the confidential Annex for more information on composition.

8.2. Other relevant information

Please refer to the confidential Annex for more information on the boundary composition of the Substance.

9. Physicochemical properties

Table 9-1 Overview of physicochemical properties

Property	**Value**
Physical state at 20°C and 101.3 kPa	Clear liquid
Melting point	Pour point: 6 ± 3 °C at 101.3 kPa *Pour point has been determined by ASTM Method D97, as recommended in the OECD 102 guideline.* *A melting point could not be observed using the differential scanning calorimetric (DSC) method because an endothermic event was not observed in the heat flow vs temperature plot. The pour point (the lowest temperature at which the test substance is first observed to flow on warming) is an appropriate measurement for viscous liquid substances.*
Boiling point	Decomposition: 303 °C at 101.3 kPa *Boiling point has been determined according to OECD 103 guideline (distillation method). The Substance degrades before boiling according to a thermal gravimetric analysis (TGA).*
Relative density	0.98 at 20 °C *The density has been determined according to the OECD guideline 109.*
Vapour pressure	$8.54.10^{-4}$ Pa at 25 °C *The vapour pressure has been determined according to ASTM D2879 method (isoteniscope). The vapour pressure was measured under different temperatures and the values were extrapolated by linear extrapolation to estimate the vapour pressure at 25 °C.*
Surface tension	Not relevant *According to the REACH guidance on information requirements and chemical safety assessment, chapter R7A, surface tension is not expected. It is not a desired property and the water solubility is below 1 mg/L at 20 °C. Thus, according to REACH annex VII, a study does not need to be conducted.*
Water solubility	<0.05 mg/L *The water solubility has been determined by the flask method according to the OECD guideline 105 (HPLC method). The Substance was not observed in the water sample at the limit of quantification (<0.6 mg/L).* Subsequent studies have improved this limit of quantification to 0.05 mg/L (50 ppb). The substance's solubility is believed to be at or slightly below this improved limit of quantification.
Partition coefficient n-octanol/water (Log K_{ow})	Log K_{ow} (Log P_{ow})= 14 (estimation) at 25 °C and pH 7 for the UVCB substance *Log K_{ow} (Log P_{ow}) has been determined experimentally according to the OECD guideline 117 (HPLC method). Estimation were based on regression analysis of retention time and capacity factor of Butyl benzene, diethylhexyl phthalate (DEHP), diisononylphthalate (DINP) and diisodecylphthalate (DIDP) were used as standards with known Kow's.*
Flash point	207 °C at 1013 hPa *The flash point has been determined according to ISO 2719 (closed cup method with Pensky-Martin apparatus).*

Oxidising properties	No oxidising properties *According to the REACH guidance on information requirements and chemical safety assessment, chapter R7a, the UVCB substance does not contain oxygen, fluorine and/or chlorine chemically bonded to other element than carbon or hydrogen associated with oxidising properties. Thus, according to REACH annex VII, a study does not need to be conducted.*
Dissociation constant	The *water solubility of the Substance is too low to conduct this study.*
Viscosity	15 Pa.s (15000 cps) at 15 °C and 6 Pa.s (6000 cps) at 25 °C *Viscosity has been determined according to OECD Test Guideline 114 (capillary viscometer (static) method).* *The substance is highly viscous at room temperature.*

10. Manufacture and uses

10.1. Quantities

According to ECHA CHEM, the aggregated tonnage (per year) of the Substance is between 100 – 1,000 tonnes.

10.2. Overview of uses

The Substance is used mainly as an antioxidant to stabilise polymers against degradation by ultraviolet light, in a variety of applications.

Widespread uses are included in member registration dossiers by some registrants on:
- Professional Use in Coatings and Adhesives (ERC 8c/8f);
- Consumer Use in Food Contact Polymer Articles (ERC 8c/8f, 11a);
- Consumer Use in Coatings and Adhesives (ERC 8c/8f).
- Article service life (ERC 11a)

Release to the environment of this substance is likely to occur from: indoor use, outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment) (ECHA dissemination website consulted on 27 January 2024[12])

Table 10-1 Overview of uses

Main uses	Key information
Manufacture	Manufacture of the Substance
Formulation or re-packing	Formulation of polymer as antioxidant. Substance used in the following products: polymers, adhesives and sealants and coating products.
Industrial sites	Substance used in the following products: polymers, adhesives and sealants and coating products. Substance used for the manufacture of plastic products and rubber products

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[12] https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.242.308

Professional workers	Widespread uses by professional workers notified by one registrant. Substance used in the following products: adhesives and sealants and coating products.
Article service life	Substance used as an antioxidant/stabiliser in the synthesis and compounding of polymer. For this category of use, one registrant notify the uses as widespread but not Lead registrants The Substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones) and rubber (e.g. tyres, shoes, toys). One registrant notify widespread uses. The same registrant also notified widespread consumer uses from food contact polymer articles
Consumer	One registrant notifies a widespread use: Consumer use in coatings and adhesives. The same registrant notifies widespread use of food contact polymer articles.

11. Classification and labelling

Tris(nonylphenol) phosphite (with the identifiers: EC No 247-759-6, CAS RN 26523-78-4 has a harmonised classification and labelling (ATP03) (Index No 015-202-00-4). The substance is classified as: very toxic to aquatic life, very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.

- Skin Sens 1 - H317
- Aquatic Acute 1 - H400
- Aquatic Chronic 1 - H410 (no conclusion on M-factor)

The harmonised classification and labelling of the substance was published in 2010 (RAC opinion available at: https://echa.europa.eu/documents/10162/f279875c-84f3-e85f-455b-93f0bd92246a).

As explained in section 7, the identity of tris(nonylphenol) phosphite was clarified during the Substance evaluation. Consequently, the previous EC number (EC No 247-759-6) was replaced by a List number. Therefore, the existing harmonized classification for EC No 247-759-6 does not apply to the Substance because of the change in identifiers. Modification of the substance identifiers associated to harmonised classification should be performed.

Table 11-1 Classification of the Substance

Harmonised classification (Annex VI of CLP)	Self-classification in registrations	Self-classification in C&L notifications
No harmonised classification for TNPP (List No 701-028-2)		Over 32 notifications (901 Notifiers), 15 with the same classification as harmonised one for CAS RN 26523-78-4) One notification (one Notifier) with same classification but higher M factor (10 for acute and chronic classification) No aquatic classification for 5 of the notifications (85 Notifiers) Only H400 for 2 of the notifications (87 Notifiers) Only H413 for 5 of the notifications (6 Notifiers) Only H411 for 4 of the notifications (3 Notifiers)

12. Environmental fate properties

The evaluating MSCA highlights that most of the environmental fate studies were conducted before the change of identifiers of the Substance. However, because the change in identifiers was solely due to an adequate identification as an UVCB, the test material tris(nonylphenyl) phosphite reported in the studies corresponds to tris(4-nonylphenyl, branched) phosphite and the nonylphenol reported in the medium of some studies corresponds to 4-branched nonylphenol.

12.1. Degradation

12.1.1. Abiotic degradation

12.1.1.1. Hydrolysis

The studies on hydrolysis are summarized in the following table:

Table 12.1-1 Overview of hydrolysis studies

Method	Results	Remarks	Reference
equivalent or similar to OECD TG 111 (Hydrolysis as a Function of pH) % Hydrolysis was defined as % NP Initial NP <0.1%. Contained 0.75% of triisopropanol amine, TIPA (added for hydrolytic stability) no information on test conditions (pH, temperature) Test material: tris(nonylphenyl) phosphite	Hydrolysis (in %): 0.1 after 242 h Transformation products: nonylphenol 0.1-0.15%	3 (not reliable) supporting study experimental result	Study report Unpublished study (2007)
OECD TG 111 (Hydrolysis as a Function of pH) pH 4, 7 and 9 at <19h Test material: tris(nonylphenyl) phosphite (LOD linear nonylphenol : 0,23 µg/L, initial concentration of TNPP, 0.1 and 1 µg/L))	Half-life (DT50): Supposed to be : 13 — 14 h at 22 °C Transformation products after 24 h: not detected	3 (not reliable) disregarded study experimental result	Study report Unpublished study (2001e)
OECD TG 111 (Hydrolysis as a Function of pH) pH 4, 7 and 9 at 24h Test material: tris(nonylphenyl) phosphite	No formation of nonylphenol detected. No information of the method of analysis of nonylphenol.	3 (reliable with restrictions) disregarded study experimental result	Study report Unpublished study (2004)
OECD TG 111 (Hydrolysis as a Function of pH)	No hydrolysis observed, but presence of tris(4-	2-3 (hydrolysis study not reliable. Reliable results from the	Study report Unpublished study (2021)

Method	Results	Remarks	Reference
Preliminary study (OECD TG 105 Water Solubility): elution in column of TNPP adsorbed on two carriers, C18 silical gel (pH 4, 20 and 50 °C) or glass beads (pH 6, 20 and 50 °C) Definitive test with 2h elution fractions from column with glass beads (pH 4,7, 9, 19.4°C) Test material: tris(4-nonylphenyl, branched) phosphite with <0.1% 4-bNP)	nonylphenyl, branched) phosphite not confirmed Significant release of 4-bNP in the preliminary study and the preparation of the samples for the hydrolysis study	preliminary study and during the preparation of samples for the hydrolysis test)	

The first hydrolysis studies provided tend to indicate that very limited hydrolysis occurred (Unpublished study, 2007; Unpublished study, 2001e; Unpublished study, 2004). Nevertheless, in Unpublished study (2007), despite the presence of a hydrolysis stabiliser, the amount of measured nonylphenol (assumed to be 4-bNP) was already slightly above the amounts of nonylphenol present as impurity. In the second study (Unpublished study, 2001e), hydrolysis was significant but the method of detection of nonylphenol (linear) was not appropriate for detection of the branched nonylphenol-chains contained in the tested Substance. Limited information is available in Unpublished study (2004). It is therefore not possible to conclude that no release of 4 branched nonylphenol occurred in this study.

In addition, observations in two ecotoxicological tests (see sections 13.1.2.1 and 13.1.3) are in contradiction with the hydrolysis tests results (occurrence of 3 % nonylphenol in an acute toxicity test on daphnia carried out with tris(nonylphenyl) phosphite with <0.1% of nonylphenol, increase in algae density (38% increase for growth rate, > 300% for the biomass) exposed to tris(nonylphenyl) phosphite, probably because of the release of phosphorus resulting from tris(nonylphenyl) phosphite hydrolysis. Therefore, the results of these studies do not allow to conclude on this endpoint. A similar conclusion is presented in the background document to RAC opinion for the harmonized classification of tris(nonylphenyl) phosphite.

In the Assessment of Regulatory Needs (ARN) conducted by ECHA on the Group “Triphenyphosphites and its derivates”, it is considered that phosphites can undergo hydrolysis when exposed to humidity with rates of hydrolysis depending on pH and molecular weight of the substance, with release of alkylated phenols. Hydrolysis data on other triphenylphosphites are however limited in this document.

A new hydrolysis study (test method: EU c.7/OECD TG 111) was requested in the decision SEV-D-2114516891-47-01/F with the aim to clarify the formation of 4-nonylphenol branched. To increase the dispersion of tris(4-nonylphenyl, branched) phosphite, the use of sterile silica gel was recommended as solid carriers, as described in ECHA guidance, chapter R.7b for the biodegradation (R.7.9.4.1, Modified ready Biodegradation tests and Appendix R7.9-3) and ISO (1995). Indeed, the solubility of tris(4-nonylphenyl, branched) phosphite is low (<0.1 mg/L), and this method has been already successfully applied to triphenyl phosphite (EC No 202-908-4).

However, the study (Unpublished study, 2021) provided in response to this decision did not follow these recommendations. The registrant used other solid supports (glass beads or C18 silica gel instead of silica gel) without explanations for this change. Moreover, they first used a continuous flow system, similar to OECD TG 105, which is a water solubility guideline to solubilize tris(4-nonylphenyl, branched) phosphite. The contact time between water and the solid phase is then lower than in a batch study. An OECD TG 111 study was then performed with elution fractions but tris(4-nonylphenyl, branched) phosphite was not measured in the elution fractions. However, the results of the preliminary studies and the initial analysis of samples used for the hydrolysis study bring information on the hydrolysis of the substance despite it is not carried out with batch conditions as it is defined in the OECD TG 111. As the study protocol is non-standard and the conclusion is mainly based on a weight of evidence from this study, methods and results are fully described below.

Preliminary study, solubilisation of tris(4-nonylphenyl, branched) phosphite

A preliminary study was carried out to generate concentrations of tris(4-nonylphenyl, branched) phosphite around its solubility limit, testing two different sorbent material (glass beads or C18 silica gel). Tris(4-nonylphenyl, branched) phosphite (50 mg) was first solubilized in pentane and then added to a solid carrier. The solvent was evaporated overnight and then the solid carrier with tris(4-nonylphenyl, branched) phosphite was added to the column. No measurement of tris(4-nonylphenyl, branched) phosphite was carried out at this stage. Therefore, 50 mg is the nominal quantity of tris(4-nonylphenyl, branched) phosphite added to the column. Deposition/ adsorption of tris(4-nonylphenyl, branched) phosphite on vessel during preparation is expected, thus the initial quantity of tris(4-nonylphenyl, branched) phosphite in the column could be lower.

The column was then filled with buffer aqueous media and the system was then equilibrated for 2 hours. The initial fraction after the 2 hours of equilibration was supposed to contain all 4-branched nonylphenol present as impurity and was eliminated. Considering that tris(4-nonylphenyl, branched) phosphite with 0.03% of 4-bNP as impurity was used for the test, this first fraction should contain 15 µg of 4-bNP. However, no measurement was carried out on this fraction, therefore, the evaluating MSCA assumes that no 4-branched nonylphenol was then present as impurity in the column after this first 2 hours elution.

A water flow rate of 14mL/hour was then applied and fractions of 1 hour were collected.

Two conditions were tested for each solid support. For C18 silica gel, pH 6 and 20°C, and pH 4 and 50°C were applied. For the glass bed, pH 4 and 20°C or 50°C were applied. According to the report, for C18 silica gel, six eluted fractions were collected on the first day, flow was stopped during the night and 8 eluted fractions were collected on the second day. Data on the 6th fraction is however missing and it is not clear if the 7th fraction correspond to the first one after the night stop. For glass beads, because of a technical issue, only the five first fractions were analysed for the pH4 and 50°C. At 20°C, 19 fractions were collected, but there is no information regarding the timeline of sample collection.

4-branched nonylphenol was then analysed (LOD = 46 ng/L for 4-branched nonylphenol and 0.2 ng/L for linear 4-nonylphenol).

Results from C18 silica gel preliminary test

At pH4 and 50°C an average concentration of 1.17 ± 0.09 mg/L of 4-bNP was measured (excluding the first fraction where 0.48 mg/L 4-bNP was measured). The concentration in the 7th fraction (the first one after the night stop) was slightly higher (1.35 mg/L). Linear NP was below LOD.

Considering 14 fractions of 14 mL (total volume of 196 mL), an average concentration of 4-bNP of 1.17 mg/L in 13 fractions and 0.48 mg/L in the first fraction, the total mass of 4-bNP recovered is 219.7 µg of 4-bNP (in 14 hours). This amount is higher than the quantity of 4-bNP initially present as impurity in the column (15 µg).

The percentage of formation of degradation products is often derived from studies with a radiolabeled substance, the substance being radiolabeled once in most of cases. As no radiolabeling was applied in this test, the percentage of 4-bNP formed is calculated comparing the weight of released 4-bNP to the nominal weight of tris (4-nonylphenyl, branched) phosphite (50 mg). It should be reminded that 50 mg is the nominal quantity added to the C18 silica gel, but no measurement was carried out to ensure that this nominal quantity was achieved. Therefore, the quantity of tris (4-nonylphenyl, branched) phosphite adsorbed onto support in the column could be lower and the percentage of hydrolyzed tris (4-nonylphenyl, branched) phosphite higher. For this preliminary test, the percentage of formation of 4-bNP is 0.44% (on weight basis). In that case the tris (4-nonylphenyl, branched) phosphite is considered fully hydrolysed leading to the formation on 3 mol of 4-bNP/mol of TNPP.

No 4-branched nonylphenol was detected from the C18 silica gel test at pH 6 and 20°C. It is not known if the hydrolysis of tris(4-nonylphenyl, branched) phosphite adsorbed on C18 silica gel is limited by the lower temperature or the higher pH.

Results from glass beads preliminary test

Glass beads, pH4, 50°C

Lower concentrations of 4-bNP were measured with the glass beads material in same conditions: an average concentration of 236 ±13 µg/L of 4-bNP was measured. The concentrations appear to be stable in the fractions, however only 5 fractions were collected in this preliminary test.

Considering 5 fractions of 14 mL (total volume of 70 mL), an average concentration of 4-bNP of 236 µg/L in each fraction, the total amount 4-bNP recovered in 5 h is 16.5 µg of 4-bNP. The percentage of mass of 4-bNP formed compared to the mass of tris(4-nonylphenyl, branched) phosphite is 0.033% w/w in 5 h.

Glass beads, pH6, 20°C

Similar concentrations were measured at pH 6 (indicated as pH 3.93 in the study report, but a mistake was recognized by the registrant) and 19.4°C: an average concentration of 256 ± 53 µg/L of 4-bNP was measured.

The reason why the number of collected fractions differs depending on the carrier, temperature and pH is not explained in the report. Considering 19 fractions of 14 mL (total volume of 266 mL), with an average concentration of 4-bNP of 256 µg/L in each fraction, the total amount of 4-bNP recovered in 19h is 68.1 µg of 4-bNP. The percentage of mass of 4-bNP formed compared to the mass of tris(4-nonylphenyl, branched) phosphite is 0.14% w/w in 19h.

Conclusion on the preliminary study

Although these tests are not usual hydrolysis studies, they show that in less than 24 hours 4-bNP can be released from tris(4-nonylphenyl, branched) phosphite in water in amounts (220 µg (C18 silica gel, 14h), 16.5 µg (glass beads 50°C, 5h); 68 µg (glass beads 20°C, 19h)) higher than the impurity initially present (15 µg, assumed to be removed in the first eluted fraction). It should be noted that with this column elution device, the amounts of released 4-bNP depend on the number of elution fractions collected. Indeed, the concentration of 4-bNP in the elution fraction is relatively constant (relative standard deviation RSD <10% at 50°C, 20% at 20°C), and it is assumed that higher elution time fractions would lead to higher amounts of released 4-bNP.

The data support that the hydrolysis occurred from tris(4-nonylphenyl, branched) phosphite adsorbed on both tested carriers. Indeed, considering the highest estimation of solubility of tris(4-nonylphenyl, branched) phosphite (50 µg/L, based on LOD) and that all the solubilised tris(4-nonylphenyl, branched) phosphite is fully hydrolysed into 4b-NP, the amount of released 4-bNP would be 9.4 µg (C18 silica gel, 50°C), 3.4 µg (glass beads 50°C) and 12.8 µg (glass beads 20°C). Higher amounts of 4-bNP are obtained through the elution column which indicates that hydrolysis of tris(4-nonylphenyl, branched) phosphite which is adsorbed on solid phase as C18 silica gel and glass beads occurred during these preliminary studies. Therefore, this study supports the release of 4-bNP from the hydrolysis of tris (4-nonylphenyl, branched) phosphite adsorbed on sediment.

These tests are not performed with a radiolabeled substance, and it is not obvious to derive a percentage of 4-bNP formation. Nevertheless, whatever stage of hydrolysis (full or partial) is considered, both tests (with C18 silica gel or glass beads) show significant formation of 4-bNP. Moreover, these percentages are calculated considering the nominal quantity of tris(4-nonylphenyl, branched) phosphite in the column, despite no measurement of tris(4-nonylphenyl, branched) phosphite has been performed. It is therefore not excluded that adsorption on to the vessel occurred during the preparation and that the quantity of tris(4-nonylphenyl, branched) phosphite in the column was lower (and the derived percentage higher). The contact time of tris(4-nonylphenyl, branched) phosphite with water might also be lower than in a standard hydrolysis tests carried out in batches (120h). Therefore, this test could be considered as a better case method, as higher amounts of 4-bNP could have been released within 120h of the batch hydrolysis study. The tests have been performed under environmentally relevant conditions and demonstrate significant release of 4-bNP. It should be noted that glass beads have a lower specific surface area (0.5 m^2/g, Naderi et al 2012) than sediment (6-46 m^2/g, 60 UK sediment samples, Rawlings et al. 2010). Therefore, higher dispersion of tris(4-nonylphenyl, branched) phosphite and availability for hydrolysis could be expected with sediment.

Table 12.1-2 Release of 4-bNP in the preliminary study

Sorbent	T°C	pH	Number of fractions /duration	Total volume (mL) (14mL / fraction	[mean 4-bNP] (µg/L)	Mass 4-bNP (µg)[1]	% released 4-NP w/w[2]	% released 4-NP mol/mol[3]
C18	50	4	13 +1	182 +14	1170 (one fraction at 480)	219.7	**0.44**	**1.37**
Glass beads	50	4	5	70	236	16.5	**0.033**	**0.1**
Glass beads	20	6	19	266	256	68.1	**0.14**	**0.42**

[1] To be compared to the quantity of 4-bNP initially present as impurity (<15µg considering 50 mg on nominal quantity of TNPP present in the column (see note 2), despite it being assumed to be removed), and to the amount of 4-bNP released from the total hydrolysis of potentially soluble tris(4-nonylphenyl, branched) phosphite (highest estimation 50 µg/L): 9.4 µg (C18 silica gel), 3.4 µg (glass beads 50°C); 12.8 µg (glass beads 20°C).

[2] percentage based on weight of 4-bNP measured compared to nominal weight of tris(4-nonylphenyl, branched) phosphite present in the column, considering the nominal quantity of tris(4-nonylphenyl, branched) phosphite in the column (50 mg). No measurement of tris(4-nonylphenyl, branched) phosphite was carried out at this stage. Deposition/ adsorption on to the vessel during preparation is not excluded and the quantity of tris(4-nonylphenyl, branched) phosphite in the column could be lower, and percentage of hydrolysis higher. In addition, it should be noted that this calculation does not take into account the difference of molecular mass between, tris(4-nonylphenyl, branched) phosphite and 4-nonylphenol, branched..

[3] percentage based on moles of 4-bNP measured compared to nominal moles of tris(4-nonylphenyl, branched) phosphite in the column derived from nominal quantity of 4-nonylphenyl, branched) phosphite (see also note 2 regarding the limitations concerning the estimation of 4-nonylphenyl, branched) phosphite actually present in the column). This calculation is closer to the method usually applied when the parent substance is radiolabeled than to a calculation based on mass of tris(4-nonylphenyl, branched) phosphite and 4-nonylphenol, branched. Nevertheless, this calculation assumed that one mole of tris(4-nonylphenyl, branched) phosphite releases one mole of 4-nonylphenol, branched, whereas each molecule of tris(4-nonylphenyl, branched) phosphite could theoretically release up to 3 molecules of 4-nonylphenol, branched.

Hydrolysis study

An OECD TG 111 study was then performed at pH 4, 7 and 9. The starting solutions of tris(4-nonylphenyl, branched) phosphite were prepared as in the preliminary study, using the bead glass column at 19.4°C. Between 56 and 61 mg of tris(4-nonylphenyl, branched) phosphite was added to glass beads at the 3 pH, the solvent has been evaporated during the night and the column was at last equilibrated for 2 hours.

After 2 hours, 24-44 mL were collected to remove 4-bNP present as impurity in tris(4-nonylphenyl, branched) phosphite (theoretically between 17 and 18 µg considering the nominal added tris(4-nonylphenyl, branched) phosphite in the column). After 2 additional hours, between 24 and 44 mL of elution solutions were collected and then used as starting solutions for the batch hydrolysis study according to the OECD TG 111. As in the preliminary study, this elution method was applied to solubilise tris(4-nonylphenyl, branched) phosphite. According to the study report, the analysis of tris(4-nonylphenyl, branched) phosphite was attempted but it could not be quantified in the collected fractions with the available analytical methods. Therefore, there is no indication that tris(4-nonylphenyl, branched) phosphite was indeed present in the collected fractions used as starting solution for the hydrolysis study according to the OECD TG 111. During this batch hydrolysis study, only 4-bNP was measured at 6 time points for 120 hours. The average concentrations over 120h are reported for each pH in the table 12.1.3.

Table 12.1-3 Initial and average concentration of 4-bNP at 19.4 °C

pH	elution rate for the preparation of tested samples (mL/h)	Concentration, just after 2h of elution (µg/L)	Average concentration (n= 6) (µg/L)	SD (µg/L)	RSD (%)
4	19	272	250	12.2	4.9
7	22	198	187	22.8	12
9	12	171	200	24	12

The concentration of 4b-NP in the batch hydrolysis test according to the OECD TG 111 is stable during the 120 h of the test. As no tris(4-nonylphenyl, branched) phosphite was detected in the starting solutions, it is not possible to conclude whether the stable concentration of 4-NP is explained by (1) the absence of degradation of tris(4-nonylphenyl, branched) phosphite into 4-bNP during the hydrolysis study or (2) by the absence of tris(4-nonylphenyl, branched) phosphite in the starting solution or (3) a too low concentration to detect any hydrolysis product. Therefore, the determination of DT50 and hydrolysis rate constant are not possible from these hydrolysis studies.

However, it confirms that 4-bNP was released from tris(4-nonylphenyl, branched) phosphite before the hydrolysis test according to the OECD TG 111 during the preparation of the starting solutions by elutions through the column with the glass beads. During this preparation, the solution was eluted for only 2 hours (44 mL for the pH 7 column) leading to low release of 4-bNP (table 12.1-4). However, the preliminary test with glass beads at pH 6 shows a constant concentration of 4-bNP during 19 hours. Assuming a constant concentration, elution for 120 h (Hydrolysis OECD TG 111 duration) would have led to percentage of formation of nonylphenol of more than 0.8% w/w.

Table 12.1-4 Initial and average concentrations of branched 4-nonylphenol at 19 °C

pH	Total volume (mL) for 2 h	[4-bNP] (µg/L) in the starting fraction	Mass 4-bNP (µg)	Nominal Mass of TNPP in column mg	% released 4-bNP 2h[1]	% released 4-bNP 120h w/w	% released 4-bNP 120h[2] mol/mol
4	**38**	272	10.3	**56**	**0.018**	**1.11**	**3.46**
7	**44**	198	8.7	**61**	**0.014**	**0.86**	**2.67**
9	**24**	171	4.1	**56**	**0.007**	**0.44**	**1.37**

[1] percentage based on weight of 4-bNP measured compared to nominal weight of the Substance present in the column, considering the nominal quantity of tris(4-nonylphenyl, branched) phosphite in the column (50 mg). No measurement of tris(4-nonylphenyl, branched) phosphite was carried out at this stage. Deposition/adsorption on vessel during preparation is not excluded and the quantity of tris(4-nonylphenyl, branched) phosphite in the column could be lower, and percentage of hydrolysis higher. In addition, it should be noted that it does not take into account the difference of molecular mass between tris(4-nonylphenyl, branched) phosphite and 4-nonylphenol, branched.

[2] extrapolated percentage over 120h based on moles of 4-bNP measured compared to nominal moles of tris(4-nonylphenyl, branched) phosphite in the column derived from a nominal quantity of 4-nonylphenyl, branched) phosphite (see also note 1 regarding the limitations concerning the estimation of tris(4-nonylphenyl, branched) phosphite actually present in the column). This calculation is closer to the method usually applied when the parent substance is radiolabeled than to a calculation based on mass of tris(4-nonylphenyl, branched) phosphite and 4- nonylphenol, branched. Nevertheless, this calculation assumed that one mole of tris(4-nonylphenyl, branched) phosphite releases one mole of 4-nonylphenol branched, whereas each molecule of tris(4-nonylphenyl, branched) phosphite could theoretically release up to 3 molecules of 4-nonylphenol branched.

Conclusion

The concentration of 4-bNP does not vary with time during the batch hydrolysis studies according to the OECD TG 111 (5 days). However, no measure of tris(4-nonylphenyl, branched) phosphite in the starting solutions used for the hydrolysis test was carried out. It is therefore not possible to conclude on the tris(4-nonylphenyl, branched) phosphite hydrolysis from this test according to the OECD TG 111.

However, hydrolysis of tris(4-nonylphenyl, branched) phosphite with release of 4-bNP occurred in the preliminary study with release of 4-bNP >0.1% after 19h at 20°C and pH6 from glass beads. It is demonstrated that this release of 4-bNP comes from the tris(4-nonylphenyl, branched) phosphite adsorbed on glass beads. The fraction of released 4-bNP is derived from the nominal quantity of tris(4-nonylphenyl, branched) phosphite in the system. However, no measurement of tris(4-nonylphenyl, branched) phosphite was carried out. Therefore, the loss of tris(4-nonylphenyl, branched) phosphite during preparation is not excluded and the quantity of tris(4-nonylphenyl, branched) phosphite in the column could be lower, and percentage of hydrolysis higher. Since the tested conditions are closed to environmental conditions, the results of the preliminary test thus supports that such hydrolysis could occur from tris(4-nonylphenyl, branched) phosphite adsorbed in sediment allowing significant release of 4-bNP in the environment.

Similar results are obtained in the starting solutions prepared for the hydrolysis study. As the volume of the collected fractions is lower than in the preliminary study, the amounts of released 4-bNP are also lower. However, at the 3 pH, the concentrations of 4-bNP in the tested fraction are in the same range than in the preliminary study. Moreover, the concentrations over 19h of elution are quite stable in the preliminary study. Therefore, it is expected that higher elution times would lead to higher 4-bNP release. An estimation of the release expected for 120h indicated that the formation of more than 0.8% w/w of 4-bNP would have been measured.

It should be noted that the hydrolysis is observed with a continuous flow with a low amount of water in contact of the adsorbed tris(4-nonylphenyl, branched) phosphite since the specific surface area of glass beads is low. Higher releases of 4-bNP could be expected in a batch study with higher volume of water in contact with the same quantity of adsorbed tris(4-nonylphenyl, branched) phosphite.

The sorbing material was not silica gel as initially recommended. The dried silica gel is a porous solid phase with a large specific surface area (between 300 and 600 m^2/g) and a large number of silanols on its surface. This solid phase is therefore polar. The test substance would have interacted with this surface by an adsorption mechanism. Water is the solvent that has the strongest affinity with this material. During the hydrolysis test, the strong affinity of water for the silica gel should have allowed the desorption of the test substance (previously adsorbed on the silica surface as well as the 4-bNP produced by hydrolysis) thus enabling the dispersion of the test substance in the aqueous phase. This method was successfully used in a hydrolysis test with triphenyl phosphite[13].

Instead, the release of 4-bNP in environmental conditions is observed in the test using glass beads (0.5 m2/g, Naderi et al 2012). In contrast with initially recommended carrier, glass beads (fused silica) are amorphous non-porous compounds with significantly less silanol on the surface than silica. Apolar compounds such as the Substance can adsorb on its surface. However, to desorb them, an organic solvent miscible with water (methanol, acetonitrile) is required, which was not used in the provided study. Therefore, considering the characteristics of the carriers, the dispersion of the Substance is expected to be less effective on glass beads. Therefore, higher release of 4-bNP could have been obtained with silica gel as a carrier as initially recommended. Moreover, higher dispersion and availability for hydrolysis could be expected, from sediment in the environment. Indeed, literature data support that sediments have higher specific area (6-46 m2/g, 60 UK sediment samples, Rawlings et al. 2010) than glass beads. In the environment, adsorption of nonylphenol on organic matter in the sediment would also be expected. Nevertheless, irrespective of the final distribution among the environmental compartments, it is expected that hydrolysis of the substance in the environment would lead to the release of 4-nonylphenol.

12.1.1.2. Phototransformation/photolysis

12.1.1.2.1. Phototransformation in air

The studies on phototransformation in air are summarized in the following table:

Table 12.1.1.2-1 Overview of phototransformation studies

Method	Results	Remarks	Reference
(Q)SAR estimation EPIWIN model version 1.9. Test material: tris(nonylphenyl) phosphite	Half-life (DT50): 5.1 h	2 (reliable with restrictions) key study	Charles A. Staples, Ph.D (2001) Meylan, W. and PH Howard. (2000)

Tris(nonylphenyl) phosphite released to the atmosphere is expected to degrade by reaction with hydroxyl radicals. A constant rate for degradation in air of 3.28 d^{-1} with a corresponding half-life of 5.1 hours was estimated (Degradation rate constant with OH radicals: 50.6 cm^3 $molecule^{-1}$ s^{-1}).

12.1.1.2.2. Phototransformation in water

This endpoint was not assessed by the evaluating MSCA.

12.1.2. Biodegradation

12.1.2.1. Biodegradation in water

12.1.2.1.1. Screening tests

The studies on biodegradation in water (screening tests) are summarized in the following table:

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[13] https://echa.europa.eu/docume+nts/10162/fc02208b-9999-388f-440d-e25b7e03f591

Table 12.1.2-1 Overview of screening tests for biodegradation in water

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge, non-adapted OECD TG 301 D (Ready Biodegradability: Closed Bottle Test) Test material: tris(nonylphenyl) phosphite	some degradation but no long-term information Degradation of test substance: < 4% after 28 days	2 (reliable with restrictions) key study experimental result	Study report Unpublished study (2001a)
activated sludge (adaptation not specified) OECD TG 301 B (Ready Biodegradability: CO2 Evolution Test Test material: tris(nonylphenyl) phosphite	minimal biodegradation but no longer term results Degradation of test substance: 1% after 29 d	2 (reliable with restrictions) supporting study experimental result	Study report Unpublished study (1994)

The ready biodegradability of tris(nonylphenyl) phosphite was studied in both a closed bottle test (OECD TG 301D) test (Unpublished study, 2001a) and a CO_2 test performed according to OECD TG 301B (Unpublished study, 1994).

In the OECD TG 301D study, tris(nonylphenyl) phosphite solutions were inoculated with a commercial bacterial preparation (Polyseed) and incubated at 20 ± 1°C. The biological oxygen demand (BOD) of the test substance was measured at 0, 7, 14, 21 and 28 days and compared to the theoretical oxygen demand (ThOD NO_3) of the nominal concentration of tris(nonylphenyl) phosphite. Tris(nonylphenyl) phosphite concentration was 15.4 mg/L which was theoretically corresponding to a Chemical Oxygen Demand of 13.2 mg/L. Beside the tris(nonylphenyl) phosphite solution, there were 3 controls: a test control (inoculated mineral medium), a procedure control (degradation of a reference substance) and a toxicity control (degradation of the reference substance in the simultaneous presence of tris(nonylphenyl) phosphite). All controls passed the acceptability criteria of the test: oxygen depletion in the test control did not exceed 1.5 mg per litre after 28 days incubation, biodegradation of the sodium acetate reference substance met the criterion of > 60% of the $ThODNO_3$ within 14 days. Tris(nonylphenyl) phosphite did not inhibit the degradation of the reference substance by more than 25% after 14 days. Finally, the variance amongst duplicate test bottles was less than 20%. Less than 4% of tris(nonylphenyl) phosphite was biodegraded after 28 days experiment.

In the OECD TG 301B study, tris(nonylphenyl) phosphite was tested at a concentration of 18.1 mg/L. The inoculum was constituted with activated sludge collected from the sewage treatment plant of Reinach (Switzerland). The pH after collection was 7.0. Before application, the inoculum was pre acclimated to the test medium overnight. The test was performed at a temperature of 22 +/- 2°C with a carbon dioxide free air supply. To consider the very low solubility of the test substance, its preparation was as follows: a stock solution was prepared dissolving 1.36 g of test substance in 10 mL dichloromethane. From this stock solution, for each replicate, 27.2 mg (200 µL) were applied onto a filter paper as small drops. After the filter paper was completely dry (no remaining dichloromethane was present), it was cut into small pieces (10-15) and added to the test medium. Thereafter, the medium volume was completed to 1.5L with 300 mL water and the flasks were immediately connected to the CO_2 scrubber. Within few hours the filter paper was homogeneously distributed in the test medium (so that it could not be seen anymore). Only 1% of tris(nonylphenyl) phosphite was biodegraded after 29 days of experiment. Less information are provided in the IUCLID of this last study, which is therefore considered as supportive.

According to these two studies, tris(nonylphenyl) phosphite is considered as not readily biodegradable.

The identification of degradation products is often not performed in the ready biodegradation tests. However, the software Catalogic v5.16 provide degradation product predictions for a ready biodegradation test (301C). This software predicts the formation of 4-bNP. However, this result remains uncertain as the substance is not in the training set.

12.1.2.1.2. Simulation tests (water and sediments)

Simulation tests are not available in the registration dossier, a data waiving is notified for this endpoint. According to the Registrants, an OECD TG 309 water simulation study is not technically feasible given the extremely low water solubility of the Substance.

Moreover, the Registrants consider that, sediment is not anticipated to be a direct and indirect exposure route of concern given limited release to the environment. However, the evaluating MSCA notes that dispersive uses are identified for tris(4-nonylphenyl, branched) phosphite (ERC 8c/f, ERC 11a), thus release to the environment cannot be excluded.

The biodegradation of tris(4-nonylphenyl, branched) phosphite could lead to the formation of 4-bNP. 4-bNP has been identified as endocrine disruptor giving rise to equivalent level of concern. However, the evaluating MSCA accepted the waiving of an OECD TG 309 study due to the hydrolysis results supporting the release of 4-bNP that justify regulatory action and due to technical difficulties (high insolubility, high adsorption) which could complicate the performance and the interpretation of a biodegradation test.

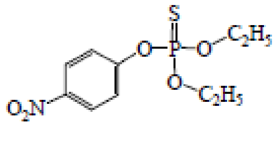
12.1.2.1.3. Summary and discussion of biodegradation in water and sediment

The ready biodegradability of tris(nonylphenyl) phosphite was studied in both a closed bottle test (OECD TG 301D) (Unpublished study, 2001a) and a CO2 test performed according to OECD TG 301B (Unpublished study, 1994). Tris(nonylphenyl) phosphite was not found to be readily biodegradable in two separate OECD TG 301 studies. In one study, 4% of tris(nonylphenyl) phosphite was found to degrade after 28 days and in another study, 1% of tris(nonylphenyl) phosphite degraded after 29 days.

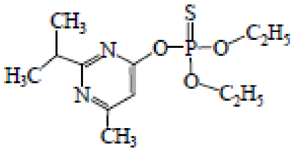
The ready biodegradation tests have shown that tris(nonylphenyl) phosphite is not readily biodegradable therefore tris(4-nonylphenyl, branched) phosphite is potentially P/vP. Nevertheless, biodegradation in the environment is not excluded. Moreover, the available data do not allow excluding the release of 4-bNP through biodegradation.

In addition, tris(4-nonylphenyl, branched) phosphite has some similarities with phosphotriesters pesticides which are one class of highly toxic synthetic organophosphates compounds. Nevertheless, they differ in the oxidation level of phosphorus. The organophosphate insecticides are primarily phosphotriesters, thiophosphotriesters, or phosphorothiolesters as shown in examples below. Organothiophosphates have therefore chemical difference with tris(4-nonylphenyl, branched) phosphite, including presence of sulfur instead of oxygen of alkylphenol. Some organosphophates contain also nitrophenol, or only alkyl chains instead of alkylphenol as ris(4-nonylphenyl, branched) phosphite.

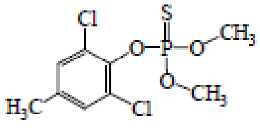
Several examples of enzymes implied in the P-O bond cleavage are reported in the literature. These enzymes differ widely in protein sequence and three-dimensional structure, as well as in catalytic mechanism, but they also share several common features. All the enzymes are metal dependent hydrolases and contain a hydrophobic active site with three discrete binding pockets to accommodate the substrate ester groups. The P-O bond cleavage occurs after oxidation of sulfur when present. Such P-O bond cleavage leading to (nitro/methyl/chloro)phenol has been shown for parathion (Munnecke and Hsieh, 1976; University of Minnesota, 2021; Sethunathan and Yoshida, 1973), fenitrothion (Roy et al, 1996), diazinon, tolclofos-methyl and chlorpyrifos (Kodaka et al, 2003; Singh et al., 2006)



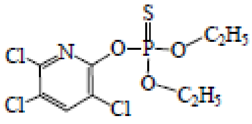
Parathion



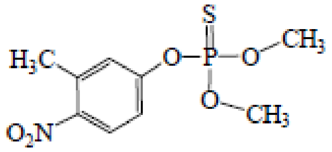
Diazinon



Tolclofos-methyl



Chlorpyrifos



Fenitrothion

Cytochrome CYP 450 enzymes could also be involved in hydrolytic P-O bond cleavage. It was for example shown for the degradation of diazinon which was mediated by cytochrome P450 in the fungal model Cunninghamella elegans (Zhao et al., 2020).

There is at present no data regarding enzymes implicated in the P-O bond cleavage of tris(4-nonylphenyl, branched) phosphite but these examples show that the occurrence of such enzymes is not excluded.

The ready biodegradation tests have shown that tris(4-nonylphenyl, branched) phosphite is not biodegradable, however, no simulation test is available to clarify the P criterion. Therefore, the evaluating MSCA concludes that tris(4-nonylphenyl, branched) phosphite is potentially P/vP. The evaluating MSCA considers that simulation testing to clarify the potential P/vP properties is not necessary at this stage, on the basis that:

- Technical difficulties with simulation testing are anticipated due to the chemical properties of the Substance (low water solubility and high hydrophobicity).
- The ED properties of the Substance were confirmed, which already allows regulatory actions to be proposed.

However, the potential P/vP properties of the Substance could be further investigated via a compliance check (CCh).

12.2. Environmental distribution

The studies on adsorption/desorption are summarized in the following table:

Table 12.2-1 Overview on adsorption/desorption data

Method	Results	Remarks	Reference
Study type: model results Model results using KOCWIN 2.00. Test material: tris(nonylphenyl) phosphite	Adsorption coefficient: log Koc: 10 — 17 at 25 °C (Results from two models)	3 (not reliable) supporting information estimated by calculation	US EPA (2010)

The estimated Koc values for tris(nonylphenyl) phosphite are far above the range of validity or validated set (log Koc = 0-7). Moreover, molecular weight of tris(nonylphenyl, branched) (689 g mol^{-1}) is above the validated domain of applicability of the models developed in KOCWIN (minimum molecular weight = 73 g mol^{-1}; maximum molecular weight = 504 g mol^{-1}). Therefore, these calculated values can only be considered as supportive data which nevertheless support high adsorption properties.

12.3. Mobility

The CLP regulation (EC No 1272/2008) indicates that a substance shall be considered to fulfil the mobility criterion (M) when the log K_{OC} is less than 3 and it can be considered to fulfil the 'very mobile' criterion (vM) when the log K_{OC} is less than 2.

No reliable experimental Koc is available in the registration dossier. However, considering the supporting data which suggest high adsorption properties of the Substance, the evaluating MSCA considers that a low concern of mobility is expected for tris(4-nonylphenyl, branched) phosphite.

12.4. Bioaccumulation

The log Kow is predicted to be over 4.5, therefore the substance is potentially B/vB.

No experimental study on bioaccumulation with fish is available in the registration dossier. The log Kow is over the 10 cut-off value (value indicative of unlikely BCF > 2,000, according to ECHA guidance Chapter R.11), nonetheless, the Kow value for TNPP was determined in a HPLC study based on a calibration curve for which the highest value was 9.3.

According to ECHA guidance Chapter R.11 (version 4.0, December 2023), other indicators for limited bioconcentration can be used in a weight of evidence approach to conclude on the B criteria, as octanol solubility, and average maximum diameter). Amongst these indicators, the octanol solubility is not available because TNPP is not stable in alcohols.

Within the framework of classification of tris(nonylphenyl) phosphite[14], an average maximum diameter over 1.7 nm was proposed for two representative isomers of tris(nonylphenyl) phosphite supporting a BCF below 2000 L kg^{-1}. Nevertheless, the software (Molecular Operating Environment software, version 2006.08)[15] used to calculate the average maximum diameter was not validated by the TC NES Technical Committee for New and Existing Substances) at that time (and more information on the structure of tris(nonylphenyl) phosphite was required under Commission Regulation (EC) No 466/2008. Supplementary information to confirm limited uptake may comprise data from toxicokinetic studies with mammals or birds and chronic toxicity study with mammals (≥ 90 days, showing no toxicity). No toxicokinetic study with mammals is available and chronic toxicities with mammals showed some low adverse effects. Despite the log Kow is assumed to be over 10 and the low chronic toxicity of tris(nonylphenyl) phosphite for mammals, available information do not allow to conclude on the B criterion for tris(nonylphenyl) phosphite.

Based on the predicted log Kow (over 4.5) the evaluating MSCA concludes that the substance is potentially B/vB, however, no experimental bioaccumulation data are available to conclude on the B criterion. The evaluating MSCA considers that further clarification of the B/vB properties at this stage is not necessary since confirmation of the ED properties of the Substance already allows regulatory actions to be proposed. However, the potential B/vB properties of the Substance could be further investigated via a compliance check (CCh).

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[14] https://echa.europa.eu/documents/10162/f279875c-84f3-e85f-455b-93f0bd92246a

13. Environmental hazard assessment

The evaluating MSCA highlights that ecotoxicity studies were conducted before the change of identifiers of tris(nonylphenyl) phosphite. However, because the change in identifiers was solely due to an adequate identification as an UVCB, the test material tris(nonylphenyl) phosphite reported in the studies corresponds to tris(4-nonylphenyl, branched) phosphite and the nonylphenol reported corresponds to 4-branched nonylphenol.

13.1. Aquatic compartment (including sediment)

13.1.1. Fish

13.1.1.1. Short-term toxicity to fish

The results are summarized in the following table:

Table 13.1-1 Overview of short-term data on fish

Method	Results	Remarks	Reference
Oncorhynchus mykiss static OECD TG 203 (Fish, Acute Toxicity Test) Test material: tris(nonylphenyl) phosphite (high purity 99.8%) Nominal tested concentrations: 0, 1.6, 3.1, 6.3, 12.5, 25.0, 50.0, and 100.0 mg/L	LL50 (96 h): > 100 mg/L (meas. (not specified)) based on: mortality	2 (reliable with restrictions) key study experimental result	Study report Unpublished study (2001b)
Leuciscus idus static DIN-Vorschrift 38412-L15 Test material: tris(nonylphenyl) phosphite commercial grade; no further information available Nominal tested concentrations: 5.8, 10, 18, 32, 58 and 100 mg/L	LC50 (48 h): 7.1 mg/L (nominal)	3 (not reliable) disregarded study experimental result	Study report Unpublished study (1988)
Brachydanio rerio (new name: Danio rerio) static EU Method C.1 (Acute Toxicity for Fish) (Cited as Directive 84/449/EEC, C.1 ("Acute toxicity for fish")) Test material: tris(nonylphenyl) phosphite (purity > 94%) Nominal tested concentrations: 10, 18, 32, 58 and 100 mg/l	LC50 (96 h): < 10 mg/L LC50 (48 hr) (96 h): 16 mg/L LC50 (24hr) (96 h): 29 mg/L	3 (not reliable) disregarded study experimental result	Study report Unpublished study (1992b)

Three acute toxicity studies on fish were provided. Two were considered as not reliable. All fish died in the study with *Brachydanio rerio* whereas a LC50 of 7.1 mg/L was determined in the study with *Leuciscus idus*. In both studies, tested concentrations (> 5 mg/L, nominal) were far above the solubility of tris(nonylphenyl) phosphite and no equilibration time was carried out to allow at least partial dissolution of tris(nonylphenyl) phosphite. It is therefore not clear that the maximum solubility was achieved in the test medium. In the test with

Brachydanio rerio, amounts of undissolved tris(nonylphenyl) phosphite were observed in all tested concentrations. In the study with *Leuciscus idus* very high amounts of solvent (until 950 mg/L DMF for the highest tested concentration) were used and there is no clear report on the effect of the solvent on fish. Additionally, no direct or indirect measures of the test concentrations were reported and it is not clear if fish were exposed to TNPP. Moreover, the potential presence of nonylphenol as an impurity of the test substance does not allow excluding that the observed effects result from nonylphenol toxicity considering toxicity reported in the EU RAR for nonylphenol (LC50 = 0.128 mg/L).

High concentrations were tested in the key study (100 mg/L, nominal). Nevertheless, the stock solution was equilibrated for 78h and decanted before dilutions for the tests. No toxicity was observed. No measurement of tris(nonylphenyl) phosphite was carried out. The purity of test tris(nonylphenyl) phosphite was high and the content of 4-bNP as impurity should have been low. The occurrence of 4-b NP as hydrolysis product was investigated and no 4-b NP was detected (detection limit of 0.2 mg/L). However, information about the analytical methods are very scarce. This key study indicated that no toxicity of tris(nonylphenyl) phosphite to fish is expected at its water solubility limit.

Overall, the evaluating MSCA considers that tris(nonylphenyl) phosphite is not expected to be toxic to fish in short-term (96 h) studies at its limit of water solubility.

13.1.1.2. Long-term toxicity to fish

No information is available in the registration dossier, the registrants waived the study on the basis that there are no effects in fish in short-term studies at concentration well in excess of the tris(nonylphenyl) phosphite water solubility limit. For the registrants, fish should not be the most sensitive species for long-term aquatic toxicity testing. The evaluating MSCA only agrees that acute toxicity studies support that invertebrates are the most sensitive trophic level, nevertheless, long term studies are usually required for poorly water soluble substances.

13.1.2. Aquatic invertebrates

13.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 13.1-2 Overview of short-term data on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna Freshwater, static OECD TG 202 (Daphnia sp. Acute Immobilisation Test) Test material (EC name): tris(nonylphenyl) phosphite (<0.1% 4 nonylphenol) Tested loads (see text): 5.00, 2.50,1.25, 0.63, 0.31, 0.16, 0.08, and 0.04 mg/L)	EL50 (48 h): 0.3 mg/L (nominal))	2 (reliable with restrictions) key study experimental result	Study report Unpublished study (2001c)
Daphnia magna static EU Method C.2 (Acute Toxicity for Daphnia) (Cited as Directive	EC50 (48 h): 0.42 mg/L (nominal)	3 (not reliable) disregarded study	Study report Unpublished study (1992c)

Method	Results	Remarks	Reference
84/449/EEC, C.2 (Acute toxicity for Daphnia)) Test material (EC name): tris(nonylphenyl) phosphite Nominal tested concentrations 0.058, 0.1, 0.18, 0.32, 0.58 and 1.0 mg/L			

The key study was run at loading levels well above the water solubility limit of tris(nonylphenyl) phosphite. The stock solution was stirred for 78 hours prior to testing to adequately mix and "age" the test solution and to allow for the solubilization/formation of hydrolysis products (water accommodated fraction). The load of the stock solution was 100 mg/L. After equilibration, the solution was decanted and the supernatant was diluted several times to obtain tested concentrations. The concentrations are expressed as nominal values taking into account the initial load of the stock solution. Detectable levels of nonylphenol (NP, 0.3 mg/L) were observed in the highest test concentration (10 mg/L, nominal load) which leads to conclude that degradation of the tris(nonylphenyl) phosphite had indeed occurred as the test substance was >99.9% pure.

The same proportion of NP was expected to occur in the other tested concentrations but was not detected (LOD = 0.2 mg/L). At 48h, an EC50 of 0.3 mg/L of solubilised/ hydrolysed tris(nonylphenyl) phosphite (nominal load) was determined, which would correspond to a concentration of nonylphenol of 0.009 mg/L. This concentration is above the water solubility of tris(nonylphenyl) phosphite. Nevertheless, it is expressed as nominal load and it should be kept in mind that actual concentrations in the test were probably lower. At last, the influence of nonylphenol in the observed toxicity is not completely elucidated. Indeed, the EC50 of nonylphenol in the RAR (2002)[16] is higher (EC50 = 0.085 mg/L), than the supposed concentration of nonylphenol leading to 50% of immobilisation in the key test.

A similar result is reported for tris(nonylphenyl) phosphite in the supportive study which is however considered as RI3. Indeed, tested concentrations were far above the solubility of the Substance, no equilibration time were applied, and no analytical follow-up of concentrations was performed neither for tris(nonylphenyl) phosphite nor for its degradation product (nonylphenol). It is therefore not clear that the maximum solubility in the test medium was achieved. Moreover, the report mentions that undissolved substance was observed at all test concentrations. Due to the low purity of the tested tris(nonylphenyl) phosphite grade, the effects might also be attributed to nonylphenol present as impurity additionally to its presence as potential hydrolysis product.

Overall, in a test performed with an approach similar to the water accommodated fraction, an EC50 of 0.3 mg/L was determined (nominal, based on initial load of the stock solution). Nonetheless, the value remains above the solubility of tris(nonylphenyl) phosphite. The stock solution was decanted before the test to allow solubilisation/hydrolysis of the substance but no measurement of tris(nonylphenyl) phosphite was performed. Therefore, actual concentrations in the test were probably lower. Additionally, degradation of pure tris(nonylphenyl) phosphite to nonylphenol was demonstrated and the influence of nonylphenol in the observed toxicity is not clear. This test supports that tris(nonylphenyl) phosphite degrades in water and leads to the formation of nonylphenol.

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[16] https://echa.europa.eu/documents/10162/43080e23-3646-4ddf-836b-a248bd4225c6

13.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarized in the following table:

Table 13.1-3 Overview of long-term studies with aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna Freshwater, static, daily renewal OECD TG 211 (Daphnia magna Reproduction Test) Test material: tris(nonylphenyl) phosphite (<0.1% 4 nonylphenol) Single nominal concentration (0.1 mg/L)	LL50 (21 d): > 0.1 mg/L test mat. (nominal load) based on: reproduction (and survival) (100% WAF) NOELR (21 d): >= 0.1 mg/L test mat. (nominal) based on: reproduction (survival, and growth) (100% WAF) LOELR (21 d): > 0.1 mg/L test mat. (nominal) based on: reproduction (survival, and growth) (100% WAF)	3 (not reliable) supporting study experimental result	Study report Unpublished study (2009)

In a limit chronic test study, tris(nonylphenyl) phosphite was first dissolved in acetone (stock solution). The tested solution was renewed each day. For this purpose, the stock solution was dissolved, and the test solution was mixed for 20 to 26 hours, and the water soluble fraction was removed and used for the test. No toxicity was observed. Nevertheless, no analytical measure was carried out and it is not demonstrated that dissolution of tris(nonylphenyl) phosphite (and potential hydrolysis to NP) occurred. Additionally, feeding of daphnia occurred just after the renewal of the solution, which could have limited bioavailability of solubilised tris(nonylphenyl) phosphite because of adsorption of tris(nonylphenyl) phosphite to the food. Therefore, there is an uncertainty on the way of exposure to tris(nonylphenyl) phosphite, either through water or through water and food.

Overall, it is considered that the provided chronic study on invertebrate is not reliable.

13.1.3. Algae and aquatic plants

The results are summarized in the following table:

Table 13.1-4 Overview of studies with algae

Method	Results	Remarks	Reference
other algae: Green algae (Raphidocelis subcapitata, formerly Selenastrum capricornutum) (algae) freshwater, static OECD TG 201 (Alga, Growth Inhibition Test) Test material: tris(nonylphenyl) phosphite (High purity <0.1% NP) Tested load (see text): 100, 50.0, 25.0, 12.5, 6.3, 3.1, and 1.6 mg/L NP limit of detection 0.2 mg/L	NOEC (72 h): 100 mg/L (meas. (not specified)) based on: growth rate LOEC (72 h): > 100 mg/L (meas. (not specified)) based on: growth rate	2 (reliable with restrictions) key study experimental result	Study report Unpublished study(2001d)
Scenedesmus subspicatus (new name: Desmodesmus subspicatus) (algae)	EC50 (72 h): > 100 mg/L based on: biomass	3 (not reliable) disregarded study	Study report

Method	Results	Remarks	Reference
Freshwater, static EU Method C.3 (Algal Inhibition test) (Cited as Directive 87/302/EEC, part C, p. 89 (Algal inhibition test)) Test material: tris(nonylphenyl) phosphite (Purity > 94%) Nominal tested concentrations of 0, 1.23, 3.7, 11, 33 and 100 mg/L	NOEC (72 h): 100 mg/L based on: biomass		Unpublished study (1992a)

Effects on algae / cyanobacteria

Two studies were provided. The key study was run at loading levels well above the water solubility limit of tris(nonylphenyl) phosphite and the stock solution was stirred for 78 hours prior to testing to adequately mix and "age" the test solution and to allow for the solubilisation of tris(nonylphenyl) phosphite and formation of hydrolysis products (water accommodated fraction). The load of the stock solution was 100 mg/L. After equilibration, the solution was decanted and the supernatant was diluted several times to obtain tested concentrations. There was no measure of tris(nonylphenyl) phosphite in the test solutions. Nonylphenol was measured but not detected (LOD =0.2 mg/L). Nonetheless, the growth of algae when exposed to test solutions was significantly higher than growth of algae in control solution (38% increase for growth rate, >300% for biomass), which indicates that degradation should have occurred with release of phosphorus. As no measure of tris(nonylphenyl) phosphite concentration was carried out, it can only be considered that no toxicity of TNPP occurred at their limit of solubility. The supportive study was considered as not reliable (tested concentrations were far above the solubility of tris(nonylphenyl) phosphite no equilibration time, no analytical follow-up of concentrations was performed neither for tris(nonylphenyl) phosphite nor for nonylphenol, low purity of the tested tris(nonylphenyl) phosphite grade).

Overall, the evaluating MSCA concludes that tris(nonylphenyl) phosphite is not expected to be toxic to algae at its water solubility. The large increase in growth rate for algae exposed to tris(nonylphenyl) phosphite supports the degradation of tris(nonylphenyl) phosphite and release of phosphorus (phosphorous acid).

13.1.4. Sediment organisms

Not assessed

13.2. Terrestrial compartment

Not available information in the registration dossier.

13.3. Microbiological activity in sewage treatment systems

Not assessed.

13.4. PNEC derivation and other hazard conclusions

Not assessed.

13.5. Conclusions of the environmental hazard assessment and related classification and labelling

The Substance has already a harmonised classification related to environmental hazards (see section 11) and no change is considered needed.

14. Human health hazard assessment

Not assessed.

15. Endocrine disrupting (ED) properties assessment

15.1. Endocrine disruption – Environment

No data are available in the registration dossier about the endocrine disruption properties of tris(4-nonylphenyl, branched) phosphite.

However, there are several evidences that degradation of tris(4-nonylphenyl, branched) phosphite could lead to the formation of 4-bNP which has endocrine disruption properties. In the framework of a hydrolysis study (Unpublished study, 2021), the release of 4-bNP under environmental conditions is shown in preliminary studies carried out to prepare solubilized tris(4-nonylphenyl, branched) phosphite , which is sorbed on glass beads. These tests support that such hydrolysis with significant release of 4-bNP could occur from tris(4-nonylphenyl, branched) phosphite adsorbed in sediment. The release of 4-bNP is additionally shown in chronic ecotoxicity tests (Unpublished study, 2001c, Unpublished study, 1992a).

15.2. Endocrine disruption – Human health

Not assessed.

15.3. Conclusions of the endocrine disrupting properties assessment and related classification and labelling

4-Nonylphenol, branched have been identified as substances of very high concern and included in the Candidate List (Decision ED/169/2012 of 18 December 2012) due to their endocrine disrupting properties which cause probable serious effects to the environment.

The release of 4-bNP from tris(4-nonylphenyl, branched) phosphite is shown in a preliminary study in the framework of a hydrolysis test and the results are further supported by the observations on chronic ecotoxicity tests. Thus, the evaluating MSCA concludes that tris(4-nonylphenyl, branched) phosphite can be a source of 4-Nonylphenol, branched in the environment. Consequently, tris(4-nonylphenyl, branched) phosphite should be considered as SVHC since it gives rise to the same equivalent level of concern to those substances listed in point (f) of Article 57 of REACH Regulation.

Similarly, taking into account the criteria of new hazard classes under CLP regulation (Commission Delegated Regulation (EU) 2023/707 of 19 December 2022)[17], the Substance should be classified as ED ENV in Category 1 with the hazard statement: May cause endocrine disruption in the environment, under CLP regulation.

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[17] COMMISSION DELEGATED REGULATION (EU) 2023/707 of 19 December 2022, amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707&from=EN

16. PBT/vPvB assessment

The ready biodegradation tests have shown that tris(nonylphenyl) phosphite is not biodegradable in these test conditions. No simulation test is available to state on the P criterion. Therefore, tris(4-nonylphenyl, branched) phosphite is considered to be potentially P/vP.

The log Kow is predicted to be over 4.5, therefore the substance is potentially B/vB. No experimental study on bioaccumulation with fish is available in the registration dossier and available non experimental data (log Kow, average maximum diameter) are not sufficient or valid enough to conclude on B criterion.

The chronic aquatic toxicity studies show no effect up to the limit of solubility, which could indicate that T criterion is not fulfilled for the environment. However, in the available chronic studies, only freshly prepared solutions were tested, and no measurement of tris(4-nonylphenyl, branched) phosphite was carried out, it is thus not possible to state if organisms were exposed to tris(4-nonylphenyl, branched) phosphite.

The registrants waived the request for an OECD TG 309 water simulation study (decision SEV-D-2114516891-47-01/F) due to technical difficulties mainly linked to the chemical properties of the Substance (low water solubility and high hydrophobicity) and because the concern related to endocrine disrupting properties was confirmed by the results of the hydrolysis study (decision SEV-D-2114516891-47-01/F). The evaluating MSCA considers that further testing of simulation studies with other compartments (sediment or soil) could lead to additional technical difficulties regarding extractability and analyses.

Considering that the ED properties of the Substance were confirmed and already allow regulatory actions to be proposed, the evaluating MSCA considers that no further actions are required at this stage in relation to potential PBT/vPvB properties. However, the potential PBT/vPvB properties of the Substance could be further investigated via a compliance check (CCh).

17. Exposure assessment

According to the registration dossier, the Substance is used in the formulation of polymer antioxidants and compounds. It can be present in a wide variety of articles such as adhesives, paints, rubbers, plastics, etc. The exposure assessment was not fully addressed during the Substance Evaluation. However, the evaluation MSCA noted widespread use of the Substance by professional workers, consumers and in article service life as listed below. Exposure of sensitive populations is expected and release of the Substance to the environment can occur particularly in these scenarios. In addition, the registration dossier specify low release rates of the Substance to the environment from rubber articles e.g. toys, packaging (excluding food packaging).

During the Substance Evaluation it was concluded that tris(4-nonylphenyl, branched) phosphite can be considered as an endocrine disruptor substance for the environment due to its degradation to 4-nonylphenol, branched. The release of 4-nonylphenol, branched can lead to harmful effects on aquatic organisms and ecosystems due to their endocrine disruptor properties. Environmental exposure, particularly to surface water, is therefore of concern due to this hazard for which no safe threshold can be defined with certainty.

Widespread uses by professional workers

Product category used
- PC 1: Adhesives, sealants
- PC 9a: Coatings and paints, thinners, paint removers

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

- SU 11: Manufacture of rubber products
- SU 12: Manufacture of plastics products, including compounding and conversion

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

Consumers uses
Use name: Consumer use of coating and adhesives (us such or in a mixture)
Environmental release category
- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

Article service life
Service life name: Use of formulated polymer in manufacturing (PEST GES 3-6)
Article category (AC)
- AC10a: Rubber articles: Large surface area articles
- AC10b: Rubber articles: Toys intended for children's use (and child dedicated articles)
- AC10c: Rubber articles: Packaging (excluding food packaging)

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

Service life name: Stabilizer in polymer (PEST GES 1-2)
Article category
- AC10a: Rubber articles: Large surface area articles
- AC10b: Rubber articles: Toys intended for children's use (and child dedicated articles)
- AC10c: Rubber articles: Packaging (excluding food packaging

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

17.1. Human health

Not assessed

17.2. Environment

Not assessed

18. Risk characterisation

Not assessed

19. References

Citation	Reference
Unpublished study (1988)	Report on the test for acute toxicity test of TK 10417 to Golden Orfe (Leuciscus idus). Report no: 88 41 26. Report date: Jun 20, 1999
Unpublished study (1992a)	Report on the growth inhibition test of IRGAFOS TNPP to green algae (Scenedesmus subspicatus). Report no: 92 81 36. Report date: Aug 28, 1992
Unpublished study (1992b)	Report on the acute toxicity test of IRGAFOS TNPP to Zebra-Fish (Brachydanio rerio). Report no: 928134. Report date: Aug 28, 1992
Unpublished study (1992c)	Report on the acute toxicity test of Irgafos TNPP on Daphnia (Daphnia magna Straus 1820). Report no: 928135. Report date: Aug 28, 1992
Unpublished study (1994)	Report on the test for ready biodegradability of IRGASTAB CH 55 in the carbondioxide evolution test. Test No 94 80 08. Report date: Apr 18, 1994
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20. Abbreviations

4-bNP	Branched 4-nonylphenol
ARN	Assessment of Regulatory Needs
BOD	Biological oxygen demand
BPR	Biocidal products regulation (EU) 528/2012
CAS RN	CAS registry number
CCH	Compliance check
CLP	Classification, labelling and packaging
CMR	Carcinogen, Mutagen and/or toxic for Reproduction
CoRAP	Community rolling action plan
DMEL	Derived minimal effect level
DNEL	Derived no-effect level
EC	European community
ECHA	European chemicals agency
ED	Endocrine disruption
EU	European union
ESR	Existing Substance Regulation
EUSES	European union system for the evaluation of substances
GLP	Good laboratory practice
MSCA	Member state competent authority
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NONs	Notification of new substances
NP	Nonylphenol
OECD	Organisation for economic co-operation and development
PBT	Persistent, bioaccumulative and toxic
PMT	Persistent, mobile, and toxic
PNEC	Predicted no-effect concentration
POP	Persistent organic pollutants
PPP	Plant protection products regulation EC 1107/2009
QSAR	Quantitative structure-activity relationship
RAR	Risk assessment report
REACH	Regulation No 1907/2006 concerning registration, evaluation, authorisation, and restriction of chemicals
STOT RE	Specific target organ toxicity – repeated exposure
STOT SE	Specific target organ toxicity – single exposure
SVHC	Substances of very high concern
TG	Test guideline
TGD	Technical guidance document
TPE	Testing proposal examination
UNEP	United nations environment program
UVCB	Unknown or variable composition, complex reaction products or of biological materials.
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile