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Helsinki, 10 September 2020

Substance name: tris(4-nonylphenyl,branched) phosphite
EC List no: 701-028-2
CAS number: n.a.
Date of latest submission(s) considered[1]: 11 January 2019
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressee(s): Registrant(s)[2] of tris(4-nonylphenyl,branched) phosphite

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(3) of the REACH Regulation (Regulation (EC) No 1907/2006), ECHA requests you to submit the following information on the registered substance.

Environment related requests

The requested information is subject to a tiered approach, which is detailed in the following section.

1. Hydrolysis of tris(4-nonylphenyl, branched) phosphite (TNPP, the Substance) with detection and quantification of the total branched 4-nonylphenol (test method: EU C.7/OECD 111). The test has to be carried out with the high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and no hydrolytic stabilizer. Hydrolysis products including total branched 4-nonylphenol[3] have to be identified and quantified.

   If the hydrolysis study demonstrates a formation of branched 4-nonylphenol of ≥ 0.1% w/w, then requirement [2] does not need to be performed.

2. Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25/OECD 309. The test material shall be the high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and no hydrolytic stabilizer. The test shall be conducted as a pelagic test using EU representative surface water with a

[1] This decision is based on the registration dossier(s) at the end of the 12-month evaluation period /This decision is based on the registration dossier(s) on the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

[2] The terms registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

[3] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

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suspended solids concentration of approximately 15 mg dw/L (but not outside the range of 10 to 20 mg dw/L) at a temperature of 20°C. Transformation/degradation products shall be identified and reasonable attempts shall be made to quantify them. In particular the total branched 4-nonylphenol[4] shall be identified and quantified.

This decision is addressed to registrants who manufacture and import the high purity grade of the Substance with a content of the impurity branched 4-nonylphenol of < 0.1%.

You have to provide an update of the registration dossier(s) containing the requested information 1, including robust study summaries and, where relevant, an update of the chemical safety report by **15 June 2021**.

You have to provide an update of the registration dossier(s) containing the requested information 2, including robust study summaries and, where relevant, an update of the chemical safety report by **12 December 2022** when the requirement 1 indicates no formation of branched 4-nonylphenol.

Tiered testing strategy:

Requirement [1]: The information required according to point [1] above shall be generated and provided by 9 months (6 months for performing the study + 3 months to agree on who is performing the testing).

Requirement [2]: If needed depending on the outcome of requirement under point [1], the information required according to point [2] above shall be generated and provided by 27 (9+18) months.

Table 1: Summary of the tiered testing strategy

Test requested	**Conditions when to perform test**	**Deadline**
1 Hydrolysis	Unconditionally	9 (6+3) months
2 Surface water degradation	Not needed if hydrolysis shows formation of branched 4-nonylphenol ≥ 0.1% w/w.	27 (9+18) months

The deadlines take into account the time that you may need to agree on which of the registrant(s) will perform the required tests (3 months is allocated for this).

In addition to the robust study summaries, you shall submit the full study report for every

[4] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

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test by the same deadline.

The reasons of this decision and any further test specifications of the requirements are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

Who performs the testing?

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has a suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals

Authorised[5] by Christel Schilliger-Musset, Director of Hazard Assessment

[5] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on tris(4-nonylphenyl,branched)phosphite (TNPP, the Substance) and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the Substance constitutes a risk to the environment. The commercial grade TNPP with ≥ 0.1% w/w of branched 4-nonylphenol was identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) in July 2019.

Therefore, this Substance Evaluation is addressing the ED concern related to the potential release of branched 4-nonylphenol, due to hydrolysis or biodegradation of the High purity form of TNPP with < 0.1% branched 4- nonylphenol. Therefore, requests (1) and (2) apply to registrants who manufacture and/or import the high purity grade of the Substance with a content of the impurity branched 4-nonylphenol of < 0.1%.

The potential risk – environment

The identification of a potential risk is based on a combination of exposure and hazard information.

According to information in the registration dossier the Substance is used as [redacted] to stabilise polymers against [redacted] in a variety of applications as polymer [redacted] plastic, adhesives, paints, lubricants, food contact polymer articles. Moreover, the Substance has wide dispersive uses in the formulation, professional and consumer uses. Thus, significant exposure to the environment is probable.

Based on information in the registration dossier as detailed below, there is a concern that TNPP in the high purity grade may be also a source of branched 4-nonylphenol in the environment as transformation/degradation products of the Substance itself. Branched 4-nonylphenol has been identified as a group of substances with endocrine disrupting (ED) properties for which there is scientific evidence of serious effects to the environment which gives rise to an equivalent level of concern listed in points (a) to (e) of Article 57 REACH.

Based on this exposure and hazard information, there is a potential risk for the environment. As the available information is not sufficient to conclude on potential ED properties, further information is needed, as explained below.

Overall description of the concern

For the Substance, concerns for both endocrine disruption and PBT/vPvB properties have been identified.

As an intial step, it must be elucidated whether hydrolysis or biodegradation of the Substance in their high purity form could result in the formation of branched 4-nonylphenol (EC 284-325-5) in the environment. Indeed, the 4 nonyphenol[6] has been included as a

[6] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

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group of substances in the REACH Candidate List because of its environmental endocrine disrupting properties. This group is already subject to specific restrictions on its marketing and use under REACH Annex XVII and it has been identified also on the Annex X list of priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD). The WFD stipulates the cessation or phasing out of discharges, emissions and losses of priority substances within an appropriate timetable not exceeding 2026. As a consequence there is a need at EU level to regulate this substances in order to achieve cessation of emisions.

If formation of branched 4-nonylphenol is observed at or over 0.1% w/w, then the Substance in the high purity form, as it is declared in the registration dossier, will be considered for substance of very high concern (SVHC) identification based on its transformation/ degradation products. In this case, no further information to clarify the PBT/vPvB properties may be required. Consequently, the information requests in the present Decision focus on clarifying the potential formation of branched 4-nonylphenol.

However, if the requested information demonstrates that hydrolysis or biodegradation of the Substance does not result in the formation of branched 4-nonylphenol, then the concern for PBT/vPvB properties may need to be clarified. During the follow-up evaluation of the information requested in the present Decision, the evaluating MSCA will consider whether further information is still required to clarify the PBT/vPvB concern. The concern for PBT/vPvB is not assessed in this Decision, but the results of the information request 2 (biodegradation simulation study according to OECD 309) can be used to assess the P properties of the Substance and minimise the need for a second simulation study in the eventual follow-up decision making. In other words, even if the requested OECD 309 study is primarily designed to provide information on transformation/degradation products of the Substance, the results will also be useful in the follow-up to define further information needs to clarify the PBT/vPvB concern, if any.

Selection of the test material

The tests requested under requirements 1 and 2 of the present Decision must be performed using tris(4-nonylphenyl, branched) phosphite in the high purity grade of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible. In the tests the identification and quantification of the total branched 4-nonylphenol formation is requested. Analysis of total branched 4-nonylphenol allows to cover all potential isomers of branched 4-nonylphenol, which consists in numerous isomers. Ideally, the test material must be initially free from branched 4-nonylphenol and free from hydrolytic stabilizer. When tris(4-nonylphenyl, branched) phosphite contains branched 4-nonylphenol as impurity, it could bring difficulties in the interpretation of the degradation studies, particularly if the formation of branched 4-nonylphenol occurs at concentrationsin the same range as the impurity.

Besides, some compositions of tris(4-nonylphenyl, branched) phosphite can contain an additive, which is a hydrolytic stabilizer. As hydrolysis is suspected to be one way of degradation of tris(4-nonylphenyl, branched) phosphite, the presence of hydrolytic stabilizer in the test material has to be avoided for the degradation tests.

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The identity and the structure of the tested TNPP must be reported. The sample of the Substance to be used shall have a composition that is within the specifications of the Substance composition that are given by all Registrant(s) that produce or manufacture in the high purity form. It is the responsibility of all the Registrant(s) to agree on the test material and to document the necessary information on composition of the test material. The substance identity information of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the test material for the Substance subject to the present substance evaluation.

The draft decision initially required to carry out the degradation test with TNPP free from branched 4-nonylphenol as impurity. However, you indicate in your comments that testing should only be carried out with commercial form of TNPP (with >0.1% of branched 4-nonylphenol). You also indicate that the proposed testing material could be not feasible to synthetize and that this is not a form of TNPP that is placed on the market in the EU. Finally, you state that the proposed test material has no bearing on commercial TNPP and cannot be used to ascertain or hypothesise the possible hazards or properties of commercial TNPP.

However, according to the lastest update of the registration dossier, the Substance is registred in both a commercial form (with > 0.1% of branched 4-nonylphenol,) and in High purity form (with <0.1% of branched 4-nonylphenol,). Moreover, in the available acute and chronic ecotoxicity test with daphnia and in an algae test, a high purity form of TNPP was used. According to these studies, the test material contained less than 0.1% of nonylphenol. As the high purity TNPP (with <0.1% of branched 4-nonylphenol) is on the market (technically feasible to produce) and has been used in the available ecotoxicity studies, you must use it for the requested studies. In addition, the degradation studies have to be carried out without the hydrolytic stabilizer.

Environment related requests

1. Hydrolysis of tris(4-nonylphenyl,branched) phosphite with detection and quantification of the total branched 4-nonylphenol (test method: EU C.7/OECD 111)

The concern(s) identified

Information on the hydrolysis of TNPP remains unclear and the formation of branched 4-nonylphenol resulting from hydrolysis of TNPP cannot be excluded. 4-nonylphenol[7] has been identified as endocrine disruptor giving rise to equivalent level of concern according to Article 57(f) of REACH. Indeed, the provided environmental fate studies seem to indicate that no hydrolysis occurred.

Nevertheless, reported test conditions, methods of detection of 4-nonylphenol and observed results (no determination of the potential adsorption of test material on

7 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

experimental devices, no differentiation between branched 4-nonylphenol present as impurity or resulting from hydrolysis) do not allow to completely elucidate hydrolysis stability.

Additionally, observations in two ecotoxicological tests are in contradiction with the hydrolysis tests results. At first, 3% of nonylphenol was detected in an acute toxicity test with daphnia (Guterson, 2001a)[8] carried out with high purity form TNPP (with <0.1% of branched 4-nonylphenol), indicating the formation of branched 4-nonylphenol in aquatic media.

Moreover, in an algae growth inhibition test, a substantial increase in algae density (>300 %) exposed to TNPP was observed, probably because of the release of phosphorus resulting from TNPP hydrolysis ([redacted], 2001b)[9]. Nevertheless, no 4-nonylphenol analysis were performed in this study.

Both studies support that hydrolysis of TNPP can occur and the study with daphnia supports that one of the hydrolysis products could be branched 4-nonylphenol.

Why new information is needed

Two hydrolysis studies are available. The study by [redacted] (2007)[10] was carried out with a high puritiy form of TNPP, with residual 4-nonylphenol <0.1% w/w. This study showed only 0.1 % 4-nonylphenol formation after 10 days. However, the test material contained an additive, which is a hydrolytic stabilizer. Therefore, no conclusion can be drawn from this study. Besides, in a supporting study by [redacted] (2004)[11], only the formation of linear nonylphenol was measured. TNPP is synthesized with branched 4-nonylphenol and if the formation of 4-nonylphenol occurs because of hydrolysis of TNPP, branched 4-nonylphenol is expected to be formed. Therefore it is not possible to conclude on the potential formation of 4-nonylphenol through hydrolysis based on this study.

Therefore, a new hydrolysis test (test method: EU C.7/OECD 111) has to be carried out with the high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and without hydrolytic stabilizer. The analytical methods have to be

[8] [redacted] 2001c). "Acute toxicity of trisnonylphenyl phosphite (TNPP) to Daphnia magna". [redacted]

[redacted] (2001d). "Algal growth inhibition test (OECD 201) on trisnonylphenyl phosphite (TNPP) ". [redacted]

[10] [redacted] (2007). TNPP Hydrolysis Study. [redacted]

[11] [redacted] (2004). [redacted]

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adapted to detect and quantify the branched 4-nonylphenol used to synthesise the TNPP applied in the test.

What is the possible regulatory outcome

If the hydrolysis test shows a release of branched 4-nonylphenol at or above 0.1% w/w, then the Substance in the high purity form, as it is declared in the registration dossier, will be considered for substance of very high concern (SVHC) identification based on its transformation/ degradation products. Indeed 4-nonylphenol[12] has been identified as an endocrine disruptor giving rise to equivalent level of concern according to Article 57(f) of REACH. Therefore, the Substance could be considered as an SVHC based on the identified endocrine disruptor properties of 4-nonylphenol.

Considerations on the test method and testing strategy

A new hydrolysis test (test method: EU C.7/OECD 111) has to be carried out with a high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and free from hydrolytic stabilizer. The analytical methods have to be adapted to identify and quantify this form of branched 4-nonylphenol.

Besides, depending of the branching, several isomers of 4- branched nonylphenol and thus of TNPP could occur. Therefore, the identity and the structure of the tested TNPP have to be reported and the sample of the Substance to be used shall have a composition that is within the specifications of the substance composition that are given by all the Registrant(s) that produce or manufacture the high purity form.

To increase the dispersion of TNPP, the use of sterile silica gel is recommended as solid carriers, as described in Guidance R.7b for the biodegradation studies (R.7.9.4.1, Modified ready Biodegradation tests and Appendix R7.9-3) and ISO (1995)[13]. As the vapour pressure of TNPP is moderate, the recovery of TNPP must be assessed at the rotary evaporation and oven drying steps included in the procedure. Analytical controls with branched 4- nonylphenol, silica gel and the buffer solutions have to be performed to check that silica gel and buffer solution do not limit the 4-nonylphenol recovery. At last, any other relevant hydrolysis products have to be quantified and identified.

You shall submit a full study report. Considering the complexity of the case and the proposed test adaptations, a complete rationale and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistical analysis, and to efficiently clarify the concern for formation of branched 4-nonylphenol.

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12 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

13 ISO *10634 (1995)* Water quality -- Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium

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Consideration of alternative approaches

Aerobic mineralisation in surface water tests performed at sterile conditions could be carried out to bring information on the hydrolysis issue. Nevertheless, an aerobic mineralisation in surface water study is usually carried out at only one pH. Moreover, the presence of suspended matter in the mineralisation study will induce the formation of non-extractable residues, which will make the interpretation of the results regarding the hydrolysis issue difficult.

In your comments on the draft decision, you argue that physico-chemical properties of TNPP (e.g. its low water solubility and its viscosity) limit the feasibility of the hydrolysis test. However, the available ecotoxicity tests show that hydrolysis could occur in the environment. Hydrolysis products are unknown and might comprise branched 4-nonylphenol. It is therefore relevant to investigate this property.

Besides, you provided in May 2018 an hydrolysis study carried out on triphenyl phospite (EC 202-908-4). Triphenyl phosphite has structural similarity with TNPP, which consists of triphenyl phosphite with nonylphenols. As TNPP, triphenyl phosphite has a low water solubility (<1 mg/L according to the registration data) and a high log Kow (log Kow = 6.7 according to the registration data (no Koc data available). In the provided study, a silica gel was used as a carrier to adapt the test to the physico-chemical properties of triphenyl phosphite. This adaptation allowed to successfully determine the hydrolysis half life of triphenyl phoshite. Moreover, this type of adaptation is detailed in the REACH guidance (R.7.9.4.1, Modified ready Biodegradation tests and Appendix R7.9-3) and ISO (1995)[14].

Although TNPP is less soluble and has stronger adsorption properties than triphenyl phosphite, the potential release of 4-nonylphenol in the ecotoxicity studies indicate that in natural environments, TNPP can be sufficiently available for degradation and this issue must therefore be clarified. The technical adaptations, which were applied in the reported degradation study with triphenyl phosphite could also allow to perform successfully the degradation tests with TNPP. Therefore, you should apply the technical adaptations reported in the study with triphenyl phosphite to the hydrolysis test with TNPP.

To conclude, technical adaptations as described in the guidance could allow to better investigate the potential release of branched 4-nonylphenol from TNPP, which is crucial considering the endocrine disrupting properties of 4-nonylphenol.

Conclusion

Therefore, based on the substance evaluation and in accordance with Article 46(3) of REACH Regulation, ECHA concludes that you are required to carry out the following study: Hydrolysis study with a high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and free from hydrolytic stabilizer, with analysis of TNPP

[14] ISO *10634 (1995)* Water quality -- Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium

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and total branched 4-nonylphenol and other potential relevant hydrolysis products (Test method: EU C.7/OECD 111 – OECD 23).

2. Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25. / OECD TG 309 of tris(4-nonylphenyl,branched) phosphite

The concern(s) identified

Data from ecotoxicity studies indicate that the degradation of TNPP could lead to the formation of branched 4-nonylphenol (see point 1). 4-nonylphenol[15] has been identified as endocrine disruptor giving rise to equivalent level of concern according to Article 57(f) of REACH. At present, no data allow determining if the formation of branched 4-nonylphenol results from hydrolysis and/or from biodegradation.

With a predicted high Koc value (log Koc >10), TNPP is expected to end in the soil because of the application of sludge from sewage treatment plants. However, considering the wide dispersives uses, exposure to the aquatic environnement is possible. In addition according to the Integrated Assessment and Testing Strategy for persistence assessment (Figure R.11-3 in the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT/vPvB), a surface water mineralization study should first be attempted when technically feasible. Moreover, because of high Koc of both TNPP and 4-nonylphenol, chemical analysis could be easier in a pelagic water degradation test with limited non-extractable residues (NER) formation.

Why new information is needed

Despite the identified concern detailed above, no simulation degradation studies have been provided and it is thus not clear if branched 4-nonylphenol is released as a transformation/degradation product to the environment.

What is the possible regulatory outcome

If the simulation test on ultimate degradation in surface water (OECD TG 309) shows a release of branched 4-nonylphenol, then the Substance in the high purity form (with < 0.1% of branched 4-nonylphenol), as it is declared in the registration dossier, will be considered for substance of very high concern (SVHC) identification based on its transformation/ degradation products. The matter is further explained under section 1 above.

Considerations on the test method and testing strategy

A simulation test on ultimate degradation in surface water (test method EU C.25 / OECD TG 309) has to be provided. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15

[15] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

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mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting NER in your test results you must explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER. The test shall be carried out at 20°C to enhance the potential degradation and the identification of transformation/degradation products.

The test has to be carried out with a high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as possible and free from hydrolytic stabilizer. Low concentrations of test materials (less 1 µg/L to 100 µg/L) are recommended by the OECD 309 guideline, however for the identification and quantification of transformation/degradation products, higher concentrations can be applied. The analytical methods have to be adapted to detect and quantify branched 4-nonylphenol. Besides, depending of the branching, several isomers of branched 4- nonylphenol and thus of TNPP could occur. Therefore, the identity and the structure of the tested TNPP have to be reported and the sample of the Substance to be used shall have a composition that is within the specifications of the Substance composition that are given by all the Registrant(s) that produce or manufacture the high purity form.

To increase the dispersion of TNPP it is recommended to use sterile silica gel as solid carriers as described in guidance R.7b for the biodegradation studies (R7.9.4.1, Modified ready Biodegradation tests and Appendix R7.9-3) and the ISO (1995)[5] reference. As the vapour pressure of TNPP is moderate, the recovery of TNPP must be assessed at the rotary evaporation and oven drying steps included in the procedure. Analytical controls with branched 4-nonylphenol, silica gel and the buffer solutions have to be performed to check that silica gel and buffer solution do not limit the nonylphenol recovery. At last, any other relevant transformation/degradation products have to be quantified and identified.

You shall submit a full study report. Considering the complexity of the case and the proposed test adaptations, a complete rationale and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed. This will allow the evaluating MSCA to fully assess the provided information, including the statistical analysis, and to efficiently clarify the concern for formation of branched 4-nonylphenol.

Consideration of alternative approaches

Other simulation test methods are available to assess the degradation of TNPP in the environment, as degradation in soil (OECD 307) or degradation in water sediment systems (OECD 308). The high predicted Koc value supports a high adsorption to organic matter of soil and sediment and therefore a significant distribution of TNPP to these compartments. Nevertheless, the higher potential of formation of NER in the OECD 307 and 308 tests compared to the OECD 309 test could lead to difficulties in interpretating the test results. Therefore an OECD 309 test is required. Besides, if the hydrolysis study shows the formation of branched 4-nonylphenol of ≥ 0.1% w/w, the required simulation study does not need to be performed.
In your comments on the draft decision, you argue that release of TNPP in water is not

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expected during manufacture, use and service life. However, according to the available information, the Substance presents wide dispersives uses on manufacturing, professional and consumer sectors, thus releases to the aquatic compartment is probable. In addition, the risk assessment reported in your CSR used scenarios from the European Union Risk Assessment Report for TNPP[16] , wich indicate that emissions to the aquatic environment may occur. Besides, available ecotoxicity studies support that the release of branched 4-nonylphenol from TNPP takes place in the aquatic compartment. As these studies were carried out in non-sterile conditions, the 4-nonylphenol formation could result from the biodegradation of TNPP in water.

Additionally, in your comments you pointed out that it is unclear how these additional aquatic studies will support the completion of the substance evaluation (SEv). The request of this study is crucial because TNPP could be a source of the endocrine disruptor branched 4-nonylphenol in the environment. Thus, the fate of TNPP in aquatic compartment must be investigated and clarified.

In your comments on the draft decision, you argue that physico-chemical properties of TNPP (e.g. its low water solubility and its viscosity) limit the feasibility of the surface water biodegradation test. However, the available ecotoxicity tests show that degradation could occur in the environment. Transformation/degradation products are unknown and might comprise branched 4-nonylphenol. It is therefore relevant to identify and quantify potential transformation/degradation products, in particular branched 4-nonylphenol.

In reply to your comment that the OECD 309 guideline would request that "concentrations of the test substance must be below its water solubility", ECHA notes that according to paragraph 7 of the OECD 309 guideline this does not apply to the transformation part of the study.

In addition, ECHA refers to the hydrolysis study carried out on triphenyl phospite (EC 202-908-4), as described under section 1 above.

To conclude, technical adaptations as described in the guidance could allow to better investigate the potential release of branched 4-nonylphenol from TNPP, which is crucial considering the endocrine disrupting properties of 4-nonylphenol.

Conclusion

Therefore, based on the substance evaluation and in accordance with Article 46(3) of REACH, you are required to carry out the following study: Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25/OECD 309. The test has to be conducted with a high purity form of the Substance containing as little branched 4-nonylphenol (<0.1%) as

[16] https://echa.europa.eu/documents/10162/13630/trd_rar_env_france_tnpp_en.pdf/3c52a33e-5c4b-4640-b863-94198d406924

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possible and free from hydrolytic stabilizer. The test shall be conducted as a pelagic test using EU representative surface water with a suspended solids concentration of approximately 15 mg dw/L (but not outside the range of 10 to 20 mg dw/L) at a temperature of 20°C. Also transformation products shall be identified and reasonable attempts shall be made to quantify them. In particular, the total branched 4-nonylphenol[17] shall be identified and quantified.

[17] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

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Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Environment/Suspected PBT; Exposure/wide dispersive use; consumer use; Exposure to sensitive populations; high RCR; aggreagated tonnage, tris(4-nonylphenyl,branched) phosphite CAS No 26523-78-4 (EC No 247-759-6) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The competent authority of France (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was necessary in order to clarify firstly the identity of the substance and in a second stage the remaining environmental concerns. Therefore, ECHA notified the Lead registrant ([redacted]) to comment a draft decision on 29 April 2014 under Article 46(1) of the REACH Regulation to request further information to clarify the substance identity provided in the registration dossier. At the same date, another draft decision was addressed to the registrant [redacted] exclusively to clarify the presence in terms of identity and concentration levels of nonyphenolic constituents in the composition of the substance.

Following the draft decision, the Lead registrant responded to the Draft decision on 30 May 2014 and an updated registration dossier was submitted to ECHA on 25 of June 2014. The information provided in the updated registration dossier indicated that the substance manufactured or imported refers to "tris(4-nonylphenyl,branched)phosphite". Communication regarding to the change of identifiers was addressed to the registrant on 18 June 2015. Consecutive to the request, a new list number 701-028-2 was attributed for the identified substance.

Consequently, the Competent Authority of France continued the substance evaluation taking into account all information including the updated registration dossier and concluded that further information is necessary to clarify the concerns on the environment (PBT and exposure). It prepared the present decision in accordance with Article 46(3) of the REACH Regulation and submitted the draft decisition to ECHA on 08 March 2019.

Furthermore, in the course of the evaluation, the evaluating MSCA identified an additional concern regarding endocrine disruptor properties by the formation of the potential transformation/degradation product branched 4-nonylphenol, which is already identified as Substance of Very High Concern (SVHC) based on endocrine disruptor properties[18].

[18] 4-Nonylphenol, branched and linear identified as SVHC by endocrine disruptor properties : https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153

Therefore, it submitted a draft decision (Article 46(1) of REACH) to ECHA on 01 April 2019.

Decision-making

ECHA notified you of the draft decision and invited you to provide comments

(i) Registrant(s)' commenting phase

ECHA received your comments and forwarded them to the evaluating MSCA.

The evaluating MSCA took your comments into account. The identity related request has been removed and the environmental related requests has not been amended.

ii) Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision. They are reflected in the reasons (Appendix 1).

ECHA referred the draft decision, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s). You did not provide any comments on the proposed amendment(s).

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-70 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to otherwise fulfil the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the required experimental studies, the sample of the substance to be used ('test material') has to have a composition that is within the specifications of the substance composition that are given by all registrant(s). It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on the composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

In relation to the experimental studies the legal text foresees the sharing of information and costs between registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who will carry out the study on behalf of the other registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx?CaseNumber=DEC-SEV-247-759-6-1-1
Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing. If ECHA is not informed of such agreement within 90 days, it will designate one of the registrants to perform the stud(y/ies) on behalf of all of them.