EUROPEAN CHEMICALS AGENCY

Helsinki, 12 September 2018

Addressee: [redacted]

Decision number: CCH-D-2114440056-58-01/F
Substance name: O,O,O-tris(2(or 4)-C9-10-isoalkylphenyl) phosphorothioate
EC number: 406-940-1
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 17/03/2017
Registered tonnage band: 10-100

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Name or other identifier of the substance (Annex VI, Section 2.1.);**
   - **Manufacturing process**
2. **Composition of the substance (Annex VI, Section 2.3.);**
   - **Identity of the constituents**
3. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**
4. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study;**
5. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information under points 1 – 2 and point 5 and the information requested under either point 3 or point 4 in an updated registration dossier by ***19 March 2021***. You have to submit the remaining requested information under either point 3 or point 4 at the latest by ***19 January 2022***. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations 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 suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

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

Appendix 1: Reasons

1. **Name or other identifier of the substance (Annex VI, Section 2.1.)**

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations. The naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (ii) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (version 2.1, May 2017).

ECHA notes that you identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

In the description field of the reference substance included in IUCLID section 1.1 you provided the following description of the manufacturing process: [redacted]

Furthermore in the "Description of composition" field in IUCLID section 1.2 you have included the following information on the manufacturing process: [redacted]

No further information has been specified on relevant parameters, in particular on the alkyl-chain distribution of [redacted] phospite used as starting material (including the upper and lower concentration limits of each alkyl chain), on the branching of the alkyl-chain (i.e. whether the alkyl-chain is only branched or branched and linear), on the relevant operational steps missing if any and concrete operating parameters (e.g. a concrete range of temperature instead of "elevated temperature") which are crucial for manufacturing the substance.

Without such information, it is not possible to identify the registered substance.

In your comments on the draft decision you agreed to provide this information in a dossier update.

You are accordingly required to provide details of the starting materials and the manufacturing processing steps that are applied to these starting materials. The information submitted shall at least include the following:

- Information on the alkyl-chain distribution of ([redacted]) phospite used as starting material, including the upper and lower concentration limits of each alkyl chain.
- Clarity whether the alkyl-chain is only branched or branched and linear.

- Any relevant operational steps and concrete operating parameters that are crucial for manufacturing the substance.

As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description of composition" field in IUCLID section 1.2.

2. Composition of the substance (Annex VI, Section 2.3.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity. The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification.

In that respect, according to chapter 4.3 of the "Guidance for identification and naming of substances under REACH and CLP", for UVCB substances, you shall note that the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature; and
- for each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

More specifically, ECHA notes the following: you reported the presence of [redacted]% of the registered substance "*O,O,O-tris(2(or 4)-C9-10(branched)alkylphenyl) phosphorothioate*".

ECHA considers that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity. Further subdivision of this entry is required which means qualitative and quantitative compositional information of the constituents.

A number of constituents have been identified by LC-ESI-MS analysis which you have included in IUCLID section 1.4. This clearly demonstrates that further breakdown of the composition of the substance is achievable.
ECHA therefore concludes that the compositional information has not been provided to the required level of detail in section 1.2 of the registration dossier.

In your comments on the draft decision you indicated that you will conduct analytical work and provide this in a dossier update with the aim to "*strengthen to the point, that the uvcb nature of the substance is due to the fact, that the different structures occurring in the parent substance "alkylated/nonylated phenol" (more than 500 different (chiral) isomers are expected, Guenther et al, Anal Bioanal Chem (2006) 384: 542–546, DOI 10.1007/s00216-*

005-0181-8) is still by far not completely resolved. Furthermore, the subsequent synthesis of a tri-ester from such a mixture leads to a much more complex mixture additionally."

You are accordingly requested to revise the composition of the registered substance by providing appropriate information on the identity of the constituents and groups of constituents in section 1.2 of the dossier in accordance with annex VI, Section 2.3 of the REACH Regulation.

Regarding how to report the composition in IUCLID, the following applies: you shall indicate the composition of the registered substance in IUCLID section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation for substances with a high potential for adsorption to sediment. The registered substance has low water solubility < 0.21 mg/L, high partition coefficient (Log Kow predicted to be 19.0-19.9) and high adsorption coefficient (log Koc, 3.7 and 4.7), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation: *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the degradation of the substance and its degradation products. The test substance was found to be poorly biodegradable in two studies following OECD guidelines 301 B and 301 C, respectively. It is assumed that the results of simulation studies would not reveal any different findings. Therefore, simulation studies on surface water and sediment are not provided."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.4 and ECHA considers that there is a need to investigate further the degradation of the substance and determine its degradation products to complete the chemical safety assessment.

According to Annex IX, Section 9.2.1.4, column 2 of the REACH Regulation, simulation testing on sediment does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of sediment is unlikely. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable. Three biodegradation screening studies are described in the dossier. The key study

conducted according to OECD 301B yielded 2 and 4% biodegradation after 28 days at concentrations of 20.5 and 10.4 mg/L, respectively. Two supporting studies yielded similar results with <3% degradation after 28 days.

Regarding exposure of sediment, the substance has a low water solubility < 0.21 mg/L, high partition coefficient (Log Kow predicted to be 19.0-19.9) and high adsorption coefficient (log Koc, 3.7 and 4.7) indicating adsorptive properties. Furthermore, ECHA notes that uses are reported in the technical dossier for which sediment exposure cannot be excluded e.g. Environmental Release Categories (ERC) 1, 2, 4 and 9A *"use of lubricants and greases in vehicles or machinery"* and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to sediment in a number of your exposure scenarios. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

The registered substance is an UVCB substance comprised of six constituents. One of the minor constituents is identified as being [redacted], which is part of the group of nonylphenols. 4-Nonylphenol, branched and linear is already included in the candidate list of substances of very high concern as a result of endocrine disrupting effects in the environment. The group entry is described as follows in the candidate list *"substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof"*. Since the remaining constituents of this substance contain [redacted], there is a concern that biotic and/or abiotic degradation of these ester bonds under environmental conditions yields endocrine disrupting metabolites, similar to those covered by the candidate list entry. At present the chemical safety assessment does not address this concern. You have argued that further investigation of the degradation of the substance and determination of the degradation products is not required as the test substance was found to be poorly biodegradable in two OECD 301 screening studies. ECHA notes that this argumentation does not fulfil the column 2 adaptation requirements. For the reasons set out above there is concern for the degradation products of this substance which should be addressed in the chemical safety assessment. Consequently, ECHA considers there is a need to investigate further the degradation of the substance and determine the degradation products.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the NERs in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments on the draft decision, you consider that studies according to OECD TG 308 and 307 are not necessary to fulfil the information requirements of Annex IX. ECHA has addressed your comments under point 5. of this decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

4. Soil simulation testing (Annex IX, Section 9.2.1.3.)

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation for substances with a high potential for adsorption to soil. The registered substance has low water solubility < 0.21 mg/L, high partition coefficient (Log Kow predicted to be 19.0-19.9) and high adsorption coefficient (log Koc, 3.7 and 4.7), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2., column 2. You provided the following justification for the adaptation "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the degradation of the substance and its degradation products. The test substance was found to be poorly biodegradable in two studies following OECD guidelines 301 B and 301 C, respectively. It is assumed that the result of a study on biodegradation in soil would not reveal any different findings. Therefore, biodegradation studies in soil are not provided.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.3 and ECHA considers that there is a need

to investigate further the degradation of the substance and determine its degradation products to complete the chemical safety assessment.

According to Annex IX, Section 9.2.1.3, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of soil is unlikely. Three biodegradation screening studies are described in the technical dossier. The key study conducted according to OECD 301B yielded 2 and 4% biodegradation after 28 days at concentrations of 20.5 and 10.4 mg/L, respectively. Two supporting studies yielded similar results with <3% degradation after 28 days.

Regarding the exposure to soil, the substance has a low water solubility < 0.21 mg/L, high partition coefficient (Log Kow predicted to be 19.0-19.9) and high adsorption coefficient (log Koc, 3.7 and 4.7) indicating adsorptive properties. Furthermore, ECHA notes that uses are reported in the technical dossier for which soil exposure cannot be excluded, e.g. Environmental Release Categories (ERC) 1, 2, 4 and 9A *"use of lubricants and greases in vehicles or machinery"* and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to soil in a number of your exposure scenarios. ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

The registered substance is an UVCB substance comprised of six constituents. One of the minor constituents is identified as being [redacted], which is part of the group of nonylphenols. 4-Nonylphenol, branched and linear is already included in the candidate list of substances of very high concern as a result of endocrine disrupting effects in the environment. The group entry is described as follows in the candidate list "substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof". Since the remaining five constituents of this substance contain [redacted] there is a concern that biotic and/or abiotic degradation of these ester bonds under environmental conditions yields endocrine disrupting metabolites, similar to those covered by the candidate list entry. At present the chemical safety assessment does not address this concern. You have argued that further investigation of the degradation of the substance and determination of the degradation products is not required as the test substance was found to be poorly biodegradable in two OECD 301 screening studies. ECHA notes that this argumentation does not fulfil the column 2 adaptation requirements. For the reasons set out above there is concern for the degradation products of this substance which should be addressed in the chemical safety assessment. Consequently, ECHA considers there is a need to investigate further the degradation of the substance and determine the degradation products.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint. According to version 4.0, June 2017*R.7b (version 4.0, June 2017)* ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound or incorporated into the biomass. When reporting the NERs in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments on the draft decision, you consider that studies according to OECD TG 308 and 307 are not necessary to fulfil the information requirements of Annex IX. ECHA has addressed your comments under point 5. of this decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

5. Identification of degradation products (Annex IX, 9.2.3.)

Analysis of the information available in your registration dossier

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement. In the technical dossier you simply state that *"Although the substance contains a functional group which could hydrolyse hydrolysis and formation of degradation products is expected to be negligible."*

You have argued that further investigation of the degradation of the substance and

determination of the degradation products is not required as the formation of degradation products is expected to be negligible. ECHA notes that this argumentation does not fulfil the Annex IX, Section 9.2.3 column 2 adaptation requirements. For the reasons set out above in sections 3 and 4 there is concern for the degradation products of this substance which should be addressed in the chemical safety assessment.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in as also discussed in sections 3 and 4 above.

Furthermore, ECHA notes that you have not provided any adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products. ECHA considers that this information is needed for the same reasons as those described in sections 3 and 4 above.
Pursuant to Annex XIII of the REACH Regulation "*the identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products*". Information on degradation products shall also be taken into account for the exposure assessment (Annex I, section 5.2.4. of the REACH Regulation) and for the hazard assessment (e.g. column 2 of Annex X, sections 9.4 and Annex X 9.5.1 of the REACH Regulation). Finally, information on degradation products is required for the preparation of Section 12 of the safety datasheet (Annex II of the REACH Regulation).

In the OECD test guidelines for simulation testing in surface water, water-sediment and soil, it is recommended that transformation products detected at ≥10% of the applied concentration of the parent substance at any sampling time (principal metabolites) should at least be identified unless reasonably justified otherwise. The test guidelines furthermore stipulate that values lower than 10% may still be warranted depending on the specific case. In particular transformation products for which concentrations are continuously increasing or seem to be stable during the study should be considered as relevant.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

Your comments on the draft decision

In your comments on the draft decision, you argue that studies according to OECD TG 308 and 307 are not necessary to fulfil the information requirements of Annex IX. You argue that detailed information on the degradation products are available and provided in your comments.

You have used Catalogic v5.12.1, CATALOGIC 301C v.10.14 to predict the degradation products of the registered substance. ECHA notes that although the registered substance

contains constituents with differing chain lengths i.e. [redacted], you have chosen the [redacted] constituents as worst cases examples for modelling on the assumption that they are smaller and more bioavailable. Based on the physicochemical properties of the constituents of the substance ECHA can follow this logic.

You have used some typical isomers of nonylphenol "NP36" (i.e. 4-[1,1,3-trimethylhexyl]-phenol) and "NP45" (i.e. 4-[1,3,5-trimethylhexyl]-phenol) as examples of the typical branching expected in the registered substance and have used these as input to the model. ECHA notes that nonylphenol is listed as a metabolite in the predictions for both input chemicals. It is a major metabolite ([redacted] mol/mol parent) in the predictions for the constituents with "NP45" type branching and a minor metabolite ([redacted]% mol/mol parent) for the constituent with "NP36" type branching. Many of the other predicted primary metabolites could potentially be degraded further to release more nonylphenol type metabolites. Section 4 above describes the concern for nonylphenol.

The predictions provided also suggest that the type of branching has a major impact on the extent of the degradation to alkylphenol type metabolites. You state that "NP36 type" branching is more typical and that there is a lower likelihood of formation of alkylphenol type metabolites from this type of branched constituents, however, you also acknowledge that: *"it cannot be excluded that different branching might result in different quantities of alkylphenols"*. In your comments on the draft decision under point 2. you also note that "*the different structures occurring in the parent substance.....is still by far not completely resolved."*

Additionally, ECHA notes that the software used for the predictions is based on the 301 C ready biodegradability test and hence, it is not possible to quantify degradants with this software as would be the case in a biodegradation simulation test. Therefore, the provided QSAR prediction cannot fulfil the present data gap.

Consequently, ECHA considers that the concern with regard to the potential formation of nonylphenol and/or other alkylphenol degradation products remains and there is a need to investigate the extent of the degradation further in a simulation study in order to quantify the amount of such degradants.

You have argued that one simulation study should be sufficient if the results can be extrapolated to the other compartments. ECHA notes that this is allowed for in the draft decision and the deadline was set accordingly[2]. You also argue that sediment is a relevant compartment and that given the results of the degradation predictions the test material would need careful consideration in order to be representative of the registered substance, including all the potentially existing isomers of technical nonylphenol. ECHA agrees that sediment is a relevant compartment and also on the statements as regard the selection of appropriate test material.

Conclusion

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

[2] See also ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment. Version 3.0, June 2017. Figure R.11—3: Integrated Assessment and Testing Strategy for persistence assessment – maximising data use and targeting testing.

Deadline in the decision

In the draft decision communicated to you the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to a minimum of 40 months for one simulation study and 50 months for both studies. You sought to justify this request by providing a letter from a radiolabelling provider which indicates that 9 months would be needed to generate the radiolabelled test substance. You also provided a letter from your test laboratory which indicates that 24 months would be needed for one study and 36 months for both studies.

ECHA notes that the original deadline already accounts for analytical method development and reporting. However, ECHA acknowledges the difficulties described by the Registrant and the need for a carefully considered analytical program with a radiolabelled test substance. Consequently, an extension to the original deadline is granted. The new deadline is 30 months for the submission of data on one simulation study with identification of degradants and 40 months for the submission of the second simulation study.

Appendix 2: Procedural history

ECHA notes that the tonnage band for several members of the joint submission is 100 to 1 000 tonnes per year.

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 03 October 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:
ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests but amended the deadline in the decision.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

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

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.