EUROPEAN CHEMICALS AGENCY

Helsinki, 30 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114361029-51-01/F
Substance name: bis(nonylphenyl)amine
EC number: 253-249-4
CAS number: 36878-20-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 05.11.2015
Registered tonnage band: 1000+T

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.) of the registered substance;**
   - **EC and/or CAS entry**
   - **Manufacturing process**
2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
3. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance;**
4. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**
5. **In case the above studies 3. and 4. are negative: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance;**
6. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species rabbit, oral route with the registered substance;**
7. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**
8. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

9. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

10. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance (as specified in Appendix 1, section 10);**

11. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance (as specified in Appendix 1, section 11);**

12. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance (as specified in Appendix 1, section 12);**

13. **Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220 with the registered substance;**

14. **Long-term toxicity to plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or, Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance;**

15. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) and carbon transformation test, EU C.22/OECD TG 217) with the registered substance;**

16. **Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test using Spiked Sediment (OECD TG 233) with the 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 of the REACH Regulation. In order 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 an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **9 December 2019**. You shall also 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. 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, shall 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.

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EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

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

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

You identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) 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: 1.3, February 2014) - referred to as "the Guidance" thereinafter.

(i). A chemical name representative of the registered substance must be specified

The numerical identifiers used to identify the registered substance corresponds to the bis(nonylphenyl)amine. EC 253-249-4 corresponds to EC name bis(nonylphenyl)amine, and CAS 36878-20-3 corresponds to CAS name [redacted] The IUPAC name refers to [redacted]). Additionally the results of the chromatographic analysis provided in section 1.4 shows the presence of [redacted] substituted constituents.

The EC and CAS entries specified by you do not sufficiently define the identity of the registered substance since they are not not consistent with the IUPAC name and the analytical information provided. The EC and CAS entries refer to the substance with two linear nonyl chains linked to the aromatic rings whereas the IUPAC name and the results of the chromatographic analysis refer to branched nonyl substituent chains and variable level of substitution.

You shall note that the registration is currently linked to the EC number 253-249-4 in REACH-IT. However you cannot remove or modify at this stage the EC number for technical reasons. Should the substance intended to be covered by this registration refer to a different substance, you shall indicate in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 253-249-4 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". This remark will ensure an unambiguous identification of the registered substance. You shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

Similarly, the appropriate CAS entry shall be included in the "CAS information" field, if available. The current CAS entry (CAS number 36878-20-3) should be reported under the "Related CAS information" field in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

However, pending the resolution of all the incompliances highlighted in the present decision, the adaptation of the identifier can only be effective once ECHA is at least in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

(ii). Details of the manufacturing process must be specified

You have described the manufacturing process as follows:"The UVCB substance is manufactured [redacted]. This description does not include the composition of the starting materials (alkyl chain distribution and branching) neither the ratio of the starting materials.

Additionally, the details of the distillation parameters (temperature and pressure) are missing from the description.

The composition of the starting materials is one of the factors determining the composition of the registered substance. Therefore, compositional information of the starting materials (in terms of identity and upper and lower concentration levels of each group of carbon chain length for branched and/or linear alkene) is a necessary element for the identification of the registered substance itself. Additionally, the ratio of amine vs nonene would give an indication of the degree of alkylation (mono-, di- or tri-alkyl substitueted constituents). Therefore it is also one of the factors determining the composition of the registered substance.

Details on temperature and pressure of distillation are relevant for the purification step, determining which constituents are isolated.

You are accordingly requested to provide the missing information on the starting materials in terms of identity, composition and upper and lower concentration levels (of the starting materials' constituents) together with the information on the ratio of the starting materials. Details on temperature and pressure of distillation shall be reported.
As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description" field in IUCLID section 1.1.

In the comments to the draft decision concerning the "Name or other identifier of the substance", you agreed with this information requirement in the draft decision. In addition you indicated the intention to address this information requirement in an update of the registration dossier.

In the comments you:

- Acknowledge "(...) that there is a certain degree of uncertainty between the numerical identifiers(...) " and that you "(...)agree to change the numerical substance identifiers according to the guidance ECHA provides to identify the substance unambiguously(...)"

- Have provided more details on the manufacturing process description which have not been available earlier in the IUCLID dossier

The information in the comments is in line with the requests in the draft decision. However, regarding the request on the details of the distillation parameters and your proposal to instead specify the nitrogen content (w/w %) of the UVCB substance, we consider that the information is not complete because the analytical values were not yet provided. ECHA will examine the information after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted in a dossier update.

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

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, the Registrant shall note that, for UVCB substances, the following applies:

- All known constituents and all constituents present at concentrations ≥ 10% should be specified by at least an English-language IUPAC name and preferably a CAS number;
- The typical concentrations and concentrations ranges of the known constituents should be given;
- Constituents that are relevant for the classification and/or PBT assessment of the substance shall always be identified by the same identifiers, independently from their concentration;
- Unknown constituents should be identified as far as possible by a generic description of their chemical nature.

You identified the registered substance as a UVCB substance "[redacted]" and you did not report any individual constituents or group of constituents of this substance in IUCLID section 1.2.

Based on the results of the chromatographic analysis provided in section 1.4 it would be possible to subdivide the constituents into [redacted]. Other groups of constituents were also identified in the analytical report. Additionally according to the information provided in the document "[redacted]", the constituent [redacted] was also quantified at levels <[redacted]%. However, none of the groups of constituents or the individual constituents present in the registered substance were reported in section 1.2.

Therefore, you are requested to report the following compositional information in separate constituent blocks:

- Constituents with a concentration ≥ 10 % (w/w);
- Constituents relevant for classification and labelling and/or PBT assessment;
- Known constituents even if ≤ 10 % (w/w) (e.g. [redacted]);
- Constituents which are unknown need to be identified as far as possible by a generic entry describing their chemical nature.

Each constituent present at ≥ 10 %, any other known constituent and any constituent relevant for classification and/or PBT assessment of the substance will need to be specifically identified by including at least the following information for that constituent:

- Name(s) in IUPAC nomenclature
- Structural formula
- EC/CAS entry (if available)
- Minimum, maximum and typical concentration values

For groups of constituents where a generic description can be defined (e.g. [redacted]), the following information will need to be provided:

- A generic chemical name describing the group of constituents covered by the entry
- A generic structural or molecular formula EC/CAS entry (if available)
- Minimum, maximum and typical concentration values.

In addition, please note that due to the lack of differentiation between constituents and impurities, the terms "main constituents" and "impurities" should not be regarded as relevant for UVCB substances.

As for the reporting of the information in IUCLID, the composition information shall be specified in in IUCLID section 1.2.

In the comments to the draft decision concerning the "Composition of the substance", you agreed with this information requirement in the draft decision. In your comments you also note that the boundary composition will be agreed by the Registrants. ECHA Secretariat notes that also your specific composition needs to be reported. For both the compositions (boundary and legal entity specific), the identity of the constituents or groups of constituents should be indicated together with the typical, minimum and maximum concentration ranges.

ECHA will examine such information only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted in a dossier update.

3. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

An "In vitro gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

You have provided study records for a [redacted] (1989) with the analogue substance TK12340 (EC no 270-128-1), [redacted] (1978) with the test substance 4,4-dioctyldephenylamine (EC no 202-965-5) and Zeiger et al (1992). All studies were conducted according to OECD 471.

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.5: "*No data on mutagenicity are available for EC 253-249-4. However, valid tests on genotoxicity were performed with structure-related alkylated diphenylamine substances such as EC 270-128 -1. The structure is shown in the robust study summaries. The read-across substance is also a viscous alkylated diphenylamine with branched side chains. These are shorter (C4/C8) compared to C9. The substance is therefore of higher lipophility (>log Pow > 7.5) and even more insoluble in water. Both substances do not mix with water, have no extreme pH and cannot cause mechanic damage. The read-across substance is more hazardous upon repeated dose oral exposure which is considered to be due to the lower molecular weight and the resulting better uptake. They contain the same functional groups both in regard to metabolism as in regard to structural alerts for DNA binding as highlighted by the OECD (Q)SAR toolbox v3.0. Therefore, it is appropriate to apply read-across.*"

The substance characterisation of the source substance(s) need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA Practical Guide 6 "*How to report on Read-Across*" (version 2.0, December 2012) it is recommended to follow the ECHA *Guidance for identification and naming of substances under REACH and CLP* (version 1.3, February 2014) also for the source substances. This ensures that the identity of the source substance and its impurity profile allow an assessment of the suitability of the substances for read-across purposes.

In order to meet the provisions in Annex XI, Section 1.5. to predict human health effects from data for a reference substance within the group by interpolation to other substances in the group, ECHA considers that structural similarity alone is not sufficient. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

The similarities may be based on common breakdown products via physical and biological processes, which result in structurally similar chemicals. However, adequate and reliable documentation of how to support this should be provided.

ECHA notes that your adaptation does not meet the requirements of the general rule for adaptation of Annex XI; Section 1.5. because:

- You have not given details about the source substance composition or impurities. ECHA does not know what components (chemicals) are present in the source substance, and does not know therefore on what basis you predict the properties of the registered substance from these components.

- The source substance is alkylated diphenylamine with C4/C8 branching, which you claim to be similar in properties. However, although you have made various assertions in your adaptation (see above), there is insufficient detail for ECHA to evaluate these assertions. In short, ECHA considers you have not presented reliable evidence to support this claim.
- According to you the C4/C8 branched diphenylamines present a worst case scenario in term of toxicity based on repeated dose toxicity. However, the fact that the C4/C8 is more toxic in repeated dose toxicity cannot be extrapolated to lack of effects in genetic toxicity. Substances with different toxicological properties in one test do not always lead to predictable properties in another human health endpoint. Hence, further elements are needed such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s), to allow a prediction of human health properties that does not underestimate risks. ECHA considers that the requirement of Annex XI, 1.5, that human health effects may be predicted from data for reference substance(s), has not been met.
- You suggest that the source and the target substances are likely to be metabolised in a similar manner. However, you have not presented evidence of similarities in metabolism. You have not provided a basis whereby this similar metabolism could be used to predict similar human health properties.
- ECHA considers that you have argued that the human health properties of the registered substance can be predicted on the basis of similar structure and similar physico-chemical properties. Structural and physico-chemical similarity are a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural and/or physico-chemical similarity per se is sufficient to enable the prediction of human health properties of a substance, since structural and/or physico-chemical similarity does not always lead to predictable or similar human health properties. Hence, further elements are needed such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s), to allow a prediction of human health properties that does not underestimate risks. ECHA considers that the requirement of Annex XI, 1.5, that human health effects may be predicted from data for reference substance(s), has not been met.

Moreover, the information provided by you is not adequate for the purpose of classification and labelling or risk assessment and consequently the respective requirement of Annex XI 1.5 are not met.

Therefore, your adaptation of the information requirement is rejected.

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

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

In your comments to the draft decision, you indicated an agreement to conduct the requested test.

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: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

4. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. 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.
You have provided study records ([redacted], 1999, OECD TG 473) with the analogue substance TK12340 (EC no 270-128-1) and ([redacted], 1990, similar to OECD TG 473) with the analogue substance monononyl diphenylamine (EC no: 248-295-7).

However, as explained above in point 3 of this Appendix, your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.5.

Therefore, your adaptation of the information requirement is rejected.

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

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

In your comments to the draft decision, you indicated an agreement to conduct the requested test with preference to the *in vitro* mammalian cell micronucleus test (OECD TG 487).

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: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

5. In case the above tests are negative: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

You have provided study record [redacted] (1978)with the analogue substance 4,4-dioctyldephenylamine (EC no 202-965-5).

However, as explained above in point 3 of this Appendix, adaptation does not meet the general rule for adaptation of Annex XI; Section 1.5.

Therefore, your adaptation of the information requirement is rejected.

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

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comments to the draft decision, you indicated an agreement to conduct the requested test with preference to the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476).

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: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that both studies requested under 1. and 2. have negative results.

6. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material.

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

While you have not explicitly claimed a specific legal basis for adaptation, you have requested adaptation with the following statement: "*The need for testing for developmental toxicity in rabbits will be assessed once the first results of the extended one-generation-study have become available. At the moment, there is insufficient data to decide if waiving criteria can be applied or not. In addition, this substance as well as possible structural analogues are currently being assessed by the* [redacted] *Competent Authorities as part of the Chemical Management Plan. Results of the* [redacted] *assessment will affect the testing strategy for this substance.*"

However, ECHA considers that this does not correspond to any valid reason for adaptation according to Annex X, 8.7.2 Column 2 or to the general rules for adaptation in Annex XI, 1.5.

Therefore, your adaptation of the information requirement is rejected.

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

The test in the first species was carried out by using a rodent species (rats). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbits as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision, you indicated an agreement to conduct the requested test.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit) by the oral route.

7. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for:

a) *Fresh water algal growth inhibition test with Desmodesmus subspicatus - Screening test* ([redacted]., 2006; following OECD Guideline 201, but non-GLP study without analytical monitoring) with the analogue substances Benzeneamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC no 270-128-1). EC50 (72 h, nominal) > 100 mg/L based on growth rate; and
b) *Acute toxicity of the water accommodated fraction (WAF) of OS#61460Y to the freshwater alga, Selenastrum carpicornutum* ([redacted]., 1997, OECD 201, GLP, no analytical monitoring), with the analogue substance OS# 61460Y, which contains two of the main constituents of the registered substance. Based on growth rate an EC50 (72 h, nominal) of 600 mg/l and 870 mg/l (96h, nominal) was measured.

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an property-specific context.

Regarding the study under point a), ECHA notes that firstly you have not sufficiently described the composition of the source substance. Based on the name "Benzeneamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene", ECHA understands that it is a UVCB substance containing various alkylated [redacted] constituents, predominantly [redacted] side chains however no detailed breakdown of the constituents with their concentration ranges has been provided so ECHA cannot conduct a meaningful comparison of the chemical similarity between source and target substances.

Furthermore, your assumption that "[redacted] *is expected to determine at large the profiles of toxicity and ecotoxicity. The known differences between different ADPA, differences in the alkyl chain length (which are overlapping due to the UVCB nature of the ADPA) and degree of alkyl chain branching, are considered to be of minor relevance for the toxicity and ecotoxicity profiles*" is not substantiated. There is no comparison of ecotoxicity test data demonstrating the minor relevance of the alkyl chains and degree of branching. Moreover, ECHA notes that as the solution was filtered and no analyses were carried out, there is uncertainty on the level of exposure in the test media. In relation to the study under point b), ECHA notes that although according to the information on the technical dossier the test has been conducted with the source substance containing two major constituents of the registered substance description of the composition of the source and target substance were inadequate because no detailed breakdown of the constituents with their concentration ranges were reported . Therefore, ECHA is not in a position to assess the chemical similarity between source and target substances.In you comments to the draft decision you have indicated an intention to re-evaluate the above read across approach. ECHA notes that this decision does not take into account any updates after the date when the draft decision was notified to you. Any update in the technical dossier will be evaluated during the follow up process.

In you comments to the draft decision you refer to analytical monitoring data in the ECHA disseminated web-site. ECHA notes that detailed information of the registered substance and source substance or justification for the read across approach is currently not included in the technical dossier. In your comments you further state that it is not technically feasible to analyse the individual component of the UVCB substance. ECHA notes that the information in the technical dossier needs to be adequately detailed to describe the composition of the registered substance and the source substance (detailed breakdown of the constituents with their concentration ranges) if the read across approach is applied. In addition if only selected constituents are tested for aquatic toxicity, justification for why some of the constituents are considered not relevant should be provided as a part of the read across justification.

In your comments to the draft decision you consider the provided studies reliable and adequate by referring to Table R.7.8-3 in the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b stating that "*the acute lethal loading level (typically expressed as the E(L)L50) is comparable to L(E)C50 values determined for pure substances tested within their solubility range.*

It may therefore be used directly for classification. ….No Observable Effect Loading Rate (NOELR) values from chronic tests may be sufficiently low to be of the same order as the level at which most components are dissolved (or the PEC value), in which case they can be used for PNEC derivation." ECHA notes that as mentioned in this part of the guidance the EL50 can be used for classification". However, as also stated in the ECHA Guidance cited above E(L)L50 cannot be used to derive a PNEC, since partitioning in the environment will make the comparison with a PEC meaningless."

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 requirement. 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 3.0, February 2016) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

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: Algae growth inhibition test, EU C.3./OECD TG 201).

Notes for your consideration

Due to the low solubility of the substance in water and the high partition coefficient and adsorption potential, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

8. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: *"In accordance to column 2 of Reach Annex IX, long-term toxicity testing on invertebrates shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on aquatic organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the local freshwater compartment, no long term study on invertebrates is proposed."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because due to the substance properties the CSA does not allow to conclude that there would be no necessity for the data. The substance has very low water solubility (<5 µg/l) and as such the information from short-term toxicity is not suitable to define the PNEC for the aquatic compartment; column 2 of Annex VII, Section 9.1.1. states that "The long-term aquatic toxicity study on Daphnia (Annex IX, Section 9.1.5) shall be considered if the substance is poorly water soluble." ECHA Guidance on information requirements and chemical safety assessment (May 2008) R.10, chapter R.10.3. provides guidance on how to derive a PNEC for aquatic compartments.

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 requirement. 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 3.0, February 2016) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

In your comments to the draft decision, you indicated an agreement to conduct the requested test a long-term toxicity study on aquatic invertebrates according to OECD 211.

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: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.
Due to the low solubility of the substance in water and the high partition coefficient and adsorption potential, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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9. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnesmore than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) 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 9.1.6., column 2. You provided the following justification for the adaptation:*"In accordance to column 2 of Reach Annex IX, long-term toxicity tests for fish shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on aquatic organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the local freshwater compartment, no long term study on fish is provided. Therefore, and for reasons of animal welfare, a long-term toxicity study in fish is not proposed."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because due to substance properties the CSA does not allow to conclude that there would be no necessity for the data. The substance has very low water solubility (<5 µg/l) and as such the information from short-term toxicity is not suitable to define the PNEC for the aquatic compartment; column 2 of annex VIII, Section 9.1.3. states that "The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble." ECHA Guidance on information requirements and chemical safety assessment (May 2008) R.10, chapter R.10.3. provides guidance on how to derive a PNEC for aquatic compartments and ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b Table R.7.8-3 further describes what should be taken into account in PNEC derivation when substance contains many components.

ECHA acknowledges your comments on the draft decision. In your comments you disagree with the request for the long -term toxicity on fish. In this context you cite the ECHA Guidance Chapter R7b Section R.7.8.5 and the ITS in the figure R.7.8-4. and state that in the ITS it is indicated that when long term aquatic toxicity tests are warranted the Daphnia study is to be conducted first. Based on the ITS you consider that only if based on the results of the long-term Daphnia study and the application of a relevant assessment factor, RCRs are > 1, long-term fish testing may need to be conducted.

ECHA notes that when based on the short term aquatic toxicity test there is no indication about the sensitivity difference of the aquatic species, the substance is poorly water soluble and has adsorptive properties, the ITS as mentioned by you cannot be used and both long term aquatic tests are required.

In your comments you state that the study design should be adequate to derive a conclusion for the T-properties of the PBT assessment and that the choice of the constituent to be tested depends on the persistence and bioaccumulation properties. As the registered UVCB substance is included in CORAP due to the PBT concern, you propose a tiered testing strategy. You propose further that the constituent relevant for the PBT assessment should be tested. To avoid repeated vertebrate testing, you propose to postpone the request for a chronic toxicity study in fish to the SEV.

ECHA notes that data gaps in the dossier should be fulfilled before starting SEV process where the decision making is based on identified concerns. ECHA agrees with you that study design should be adequate to also provide information on the toxicity of the most relevant constituent(s) regarding the PBT assessment but this is not dependent on the outcome of the SEV process and the information on aquatic toxicity should lead to understanding of the toxic profile of the whole substance. This information is relevant in e.g. classification and labelling and CSA (derivation of the PNECaquatic). ECHA notes that as indicated in the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b Table R.7.8-3 even if the results based on acute lethal loading level can be used in the classification those results cannot be used to derive PNECaquatic since the partitioning in the environment will make the comparison with PEC meaningless.

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 requirement. 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 3.0, February 2016) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD TG 210 more sensitive that the short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215) as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth (see ECHA Guidance on information requirements and chemical safety assessment (version 3.0, February 2016), Chapter R7b, Figure R.7.8-4). Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA Guidance Chapter R7b, version 3.0, February 2016).

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: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.

Due to the low solubility of the substance in water and the high partition coefficient and adsorption potential, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

10. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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.

You have not provided any study record of sediment simulation testing in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.2., column 2. You provided the following justification for the adaptation *"In accordance with column 2 of Reach Annex IX, further biotic degradation tests shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the substance and its degradation products. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the sediment, no further degradation studies are proposed"*.
However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.2., column 2 because the substance is not readily biodegradable and the provided screening level information in the dossier leads to potentially P or vP conclusion and there is no information on the degradation products and their fate. ECHA considers that at this stage the information in the CSA is not complete due to the data gaps addressed in this decision. Therefore ECHA considers that the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA further notes that contrary to Annex XI, Section 3 of the REACH Regulation, direct and indirect exposure of the aquatic compartment cannot be excluded based on the reported uses of the substance. The Registrant has not presented any other adaptation to the current information requirement pursuant to Annex XI. Consequently, the general adaptation rules of Annex XI of the REACH Regulation do not apply. Consequently there is a need to investigate further the degradation of the substance and its degradation products.

In the technical dossier you have concluded that the substance is not readily biodegradable and that "*the UVCB substance fulfils the screening criterion persistent (P) and very persistent (vP). In the absence of further experimental data on degradation it cannot be excluded that the half-life data in the different environmental compartments are expected to be above the cut-off values for persistency given in Annex XIII of regulation 1907/2006/EC and that the UVCB is regarded as persistent (P) or very persistent (vP)*".

Taking into account the above, ECHA notes that the Registrant has not provided adequate justification in his chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the registered substance or its degradation products. As explained further below, ECHA considers that this information is needed for the PBT/vPvB assessment and for the identification of the degradation products. According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of The Guidance on information requirements and chemical safety assessment R.11 on PBT/vPvB assessment (version 2.0, November 2014), indicates that "constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). Prior to further bioaccumulation assessment it is therefore necessary to provide further information on each relevant constituent, impurity and additive relevant when they are present in concentration of ≥ 0.1% (w/w). Individual concentrations < 0.1 % (w/w) normally need not be considered.

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 3.0, February 2016) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

ECHA recognises that the registered substance has low water solubility (<5 µg/L at 20 °C and pH 6.1), high partition coefficient (log Kow ≥7.5 at 25°C) and high adsorption coefficient (log Koc, soil 7.12). Recommended test concentration on the OECD TG are in the range of <1-10 µg/L.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation,

Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. 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 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments to the Member State Competent Authority (MSCAs) PfA, you indicated the following *"in case a simulation test on ultimate degradation in surface water will be performed, we agree that the surface water can be amended with suspended solids or sediment of 0.01 to 1g/l dry weight according to OECD Guidance 309. However, we disagree to deviate from the concentration range mentioned in OECD 309 and to de-fine a smaller concentration range. The appropriate SPM concentration will be elaborated during the test once the test is being conducted".* ECHA notes the approach where the pelagic test option is recommended, with testing natural surface water containing between 10 and 20 mg SPM dw/L and reporting NER is in agreement with the discussions during MSC 51 (December 2016) and MSC 52 (February 2017) meetings.

ECHA acknowledges your comments on the request on simulation testing on ultimate degradation in surface water. ECHA notes that you agree to provide further information on the degradation of the registered substance. You propose that the constituent with highest bioaccumulation potential would be the most appropriate test material. ECHA notes that as stated above in this decision, further information is needed on all relevant constituents. ECHA agrees that the degradation testing could be performed with the constituent with the highest bioaccumulation potential provided that also justification on why some of the constituents are considered not potentially bioaccumulative and therefore not relevant to be tested should be provided.

On the other hand you propose following two alternative strategies instead of conducting simulation testing in water:

1) to perform modified/enhanced ready biodegradability study including identification and quantification of the constituents: or
2) to postpone the evaluation of persistence and determination of constituents/test material to be tested for persistence and the corresponding degradation product to the CORAP evaluation.

ECHA notes that you are free to perform screening level biodegradation tests to support the persistence assessment. The outcome of the screening tests when relevant may be used as a part of WoE or adaptation of the information requirement but cannot as such be considered as a replacement of the simulation test which derives to generate the degradation half-life in the environment and which is a standard information requirement. ECHA notes further that data gaps in the dossier should be fulfilled before starting, SEV process where the decision making is based on identified concerns.

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 mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309) at a temperature of 12 °C. You shall provide information on the degradation of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w). Alternatively, you shall provide a justification for why you consider certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment.

11. 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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of soil simulation testing in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.3.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.3., column 2. You provided the following justification for the adaptation *"In accordance with column 2 of Reach Annex IX, further biotic degradation tests shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the degradation of the substance and its degradation products. Since the Risk Characterisation Ratio of the risk assessment is below 1 for soil, no further degradation studies are proposed"*.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.3., column 2 because the substance is not readily biodegradable and the provided screening level information in the dossier leads to potentially P or vP conclusion and there is no information on the degradation products and their fate. As specified under request no. 10 above, ECHA considers that at this stage the information in the CSA is not complete due to the data gaps addressed in this decision. Therefore, ECHA considers that the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA further notes that direct and indirect exposure of the soil compartment cannot be excluded based on the reported uses of the substance. Consequently there is a need to investigate further the degradation of the substance and its degradation products.

The substance is not readily biodegradable and you conclude in the registration dossier that "*the UVCB substance fulfils the screening criterion persistent (P) and very persistent (vP). In the absence of further experimental data on degradation it cannot be excluded that the half-life data in the different environmental compartments are expected to be above the cut-off values for persistency given in Annex XIII of regulation 1907/2006/EC and that the UVCB is regarded as persistent (P) or very persistent (vP)*".

ECHA considers that further information on degradation is needed for the PBT/vPvB assessment and for the identification of the degradation products. According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation". Prior to further bioaccumulation assessment it is therefore necessary to provide further information on each relevant constituent, impurity and additive relevant when they are present in concentration of ≥ 0.1% (w/w). Individual concentrations < 0.1 % (w/w) normally need not be considered.

Furthermore, ECHA notes that the registered substance has low water solubility (<5 µg/L at 20 °C and pH 6.1), high partition coefficient (log Kow ≥7.5 at 25°C) and high adsorption coefficient (log Koc, soil 7.12), indicating adsorptive properties. In addition, the substance has widespread use as an additive in machinery lubricants so there is potential for exposure to the environment. ECHA considers that you have not demonstrated that soil exposure is unlikely.

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 3.0, February 2016) 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..

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment.

Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 307. Therefore, the test should be performed at the temperature of 12°C.

In response to a MSCAs PfA ECHA clarifies the following. 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 by covalent bonds or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

ECHA acknowledges your comments on the request on simulation testing in soil. ECHA notes that you agree to provide further information on the degradation of the registered substance and propose to perform enhanced biodegradation test and if needed follow the tiered testing strategy described in this decision. In your comments you refer to the comments you provided on the request for simulation degradation in water. However, at the same time, you repeat the option described under Appendix I section 10. of this decision to postpone the evaluation of persistence to the CORAP evaluation.

As described above in Appendix I section 10. of this decision the screening level degradation test may when relevant be used as a part of WoE or adaptation of the information requirement but cannot as such be considered as a replacement of the simulation test which derives to generate the degradation half-life in the environment. ECHA notes further that data gaps in the dossier should be fulfilled before starting SEV process where the decision making is based on identified concerns.

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) at a temperature of 12 °C. You should provide information on the degradation of all relevant of all constituents, impurities and additives present in concentration of ≥ 0.1% (w/w) is soil. Alternatively, you should provide a justification for why you consider certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment.

Notes for your consideration

Before conducting the requested tests (sections 10-11) 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 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) 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 2.0, November 2014), 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.

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

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.

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 requests 10 and 11 above.

Furthermore, ECHA notes that you have not provided any 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 in relation to the PBT/vPvB assessment. In response to a MSCAs PfA ECHA notes that further information on the relevant degradation products is also needed for the risk assessment.

In response to the MSCA PfA, you have provided information on the substituted diphenylamines (SDPAs) released by Environment and Climate Change Canada. You indicate "*in this document it was concluded that none of the 14 SDPAs assessed pose a risk to the environment or to human health and, there-fore, do not meet any of the criteria under section 64 of CEPA 1999: (http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2622BEC7-1). For this assessment exposure in multiple scenarios representing industrial activities and overall use in Canada were investigated. SDPAs were found to be primarily associated with sediments, particulate matter and soil. The field monitoring data indicate a low bioaccumulation potential*". ECHA notes that you have not outlined why you consider this information is relevant to this registration and indicated uses within EU. ECHA will assess fully the information in the follow up stage of the process.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w).*" Therefore degradation products should be identified for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

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.

You may obtain this information from the simulation study also requested in this decision, or by some other measure. In the latter case, you will need to provide a scientifically valid justification for the chosen method. 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 should provide information on the degradation products of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w). Alternatively, you should provide a justification for why you consider certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment.

ECHA acknowledges that you have provided comments on the information requests 11 and 12 with the emphasis that these comments would be covering also information required for identification of degradation products. ECHA has responded to these comments in Appendix 1 Sections 10 and 11 of this decision.

Therefore, pursuant to Article 41(1)(a) 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.

13. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification:*"Direct exposure to the terrestrial compartment is not intended. An indirect exposure to the soil compartment via sewage sludge can not be excluded, however, based on the recent exposure assessment, no risk for terrestrial organisms at any substance life cycle stage from the stage of production and formulation up to the stage of its intended use is likely. Therefore, no tests on terrestrial organisms are provided.*

Your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, because exposure to the soil compartment cannot be excluded. This is confirmed in your justification above, as well as from the reported uses in the technical dossier (ERC 8d: Wide dispersive outdoor use of processing aids in open systems). Furthermore, ECHA notes that the substance is non-volatile, has very low water solubility (<5 µg/L), it is highly adsorptive (log Koc ~7 and likely to be persistent, thus indicating a concern for the terrestrial compartment. EPM can not be used when the real PNECwater is not derived due to no effects in the short term aquatic toxicity for the poorly water soluble and adsorptive substance.

Therefore, your adaptation 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 section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logK_{ow}$ >7.5 and log Koc ~7) and is likely to be very persistent. Therefore ECHA considers that the column II adaptation for Annex IX, section 9.4 regarding long-term testing instead of short-term testing, is not applicable to this substance.

According to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach. ECHA notes that in this case, the EPM approach is not applicable as no effects are observed in the short term aquatic studies and real PNECwater cannot be derived (ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R.7b). Therefore, ECHA considers that accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the above mentioned guidance is not possible at this time. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

In your comments to the draft decision, you indicated an agreement to conduct the requested test.

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: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD TG 222), or Enchytraeid reproduction test (test method: OECD TG 220).

Notes for your consideration

If the results of the requested toxicity tests on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

14. Long-term toxicity to plants (Annex X, Section 9.4.6.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification: *"In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the soil compartment, no study on terrestrial organisms is proposed. Additionally,based on its uses, the UVCB substance is not supposed to be directly applied to soil and exposure to soil is negligible."*

Your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, because there is currently no valid PNEC for the aquatic compartment (as explained in information request 8 above) and therefore Equilibrium Partitioning Method (EPM) and RCRs based on the EPM cannot be used to predict toxicity to terrestrial organisms including terrestrial plants. Therefore, the adaptations cannot be accepted.

As established also within information request 13 above, it is not currently possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

OECD TG guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection.

Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.
ECHA acknowledges your comments on the draft decision. ECHA notes that you agree with the request on long-term toxicity testing on aquatic invertebrates, long-term toxicity to terrestrial invertebrates and effects on soil micro-organisms. In you comments you argue, as also stated in the draft decision, that if based on the results of the above test requests, the registered substance would fall into the soil hazard category 4, the long-term toxicity test with terrestrial plants is warranted. The tiered approach that you in your comments refer to is already included in this decision under "Notes for your consideration".

ECHA notes that in your comments you state that due to the substance properties the exposure to terrestrial plants would be limited and therefore not appropriate test organisms to assess the toxicity of the substance. ECHA notes that in case the substance falls into the soil hazard category 4, testing the toxicity to terrestrial plants is a standard information requirement. If waived, the justification should fulfil the specific rules outlined in column 2 of the Annex X, Section 9.4.6 or general rules in Annex XI of the REACH Regulation.

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: Terrestrial plants, growth test (test method: OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

Notes for your consideration

If the results of the requested toxicity tests on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

15. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification: "*In accordance to column 2 of REACh Annex IX, and X, toxicity testing on terrestrial organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on terrestrial organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the soil compartment, no study on terrestrial organisms is proposed. Additionally,based on its uses, the UVCB substance is not supposed to be directly applied to soil and exposure to soil is negligible.*"

Your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, because of the same reasons outlined for information request 13 above. Therefore, the adaptations 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.

ECHA notes that the tests requested under points (8 and 9) above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

In your comments to the draft decision, you indicated an agreement to conduct the requested test.

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: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD TG 216).

Notes for your consideration

If the results of the requested toxicity tests on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

16. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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.

ECHA notes that you have sought to adapt the long-term toxicity testing on sediment organisms using the following justification: *"In accordance to column 2 of Reach Annex X, long-term toxicity testing on sediment organisms shall be proposed if the result of the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. Since the Risk Characterisation Ratio of the risk assessment is below 1 for the sediment compartment, no long term study on sediment organisms is proposed. Additionally, the application of the substance during its life cycle does not result in direct exposure to sediment."*
In your proposed adaptation you claim that there is no need to investigate the effects on sediment organisms further because the RCRs are below 1 for the sediment compartment and because there is no direct exposure to sediment. As explained for information request 8 above, there is currently no valid PNEC available for aquatic toxicity to allow the use of EPM in calculating the PNECsedimentscreen for the sediment risk assessment. In the present case, in the absence of sediment toxicity data, you have derived PNECsedimentscreen using EPM. As the EPM approach is not applicable as described above, ECHA notes that you have not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms. In fact, the present substance has a high potential to adsorb to sediment (log Koc ~7) and it is likely to be persistent. Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

According to ECHA *Guidance on information requirements and chemical safety assessment* (R.7b, version 3.0, February 2016, Section R.7.8.7.) the EPM cannot be used in a weight of evidence approach for substances that are highly insoluble and for which no effects are observed in aquatic studies. For such substances at least one sediment study has to be performed. ECHA notes that in the technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a reported water solubility of <5 µg/L ECHA considers that long-term sediment testing is indicated for the registered substance.

In addition, ECHA notes that among the uses reported in the technical dossier there are wide spread used that cannot exclude exposure to sediment (ERC 8d: Wide dispersive outdoor use of processing aids in open systems). ECHA notes further that in order for an adaptation of Annex X, 9.5.1. Column 1 provisions to be justified, you would have to demonstrate by means of the Chemical Safety Report (CSR) that there is no necessity to generate the data. In establishing this, in some cases and as explained in ECHA *Guidance on information requirements and chemical safety assessment* (R.7b, version 3.0, February 2016, Section R.7.8.7.), you may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

In your comments to the draft decision, you indicated an agreement to conduct the requested test.

Therefore, in this specific case, ECHA notes that the Registrant has not justified an adaptation. 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: Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD TG 218) *or* Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD TG 225) *or* Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Sediment (OECD TG 233).

Notes for your consideration

The Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Sediment (OECD TG 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses. ECHA considers that it is your responsibility to choose the most appropriate test protocol and to give a justification for the choice. You may carry out more than one of the sediment tests defined in Section II above if you consider that further testing is required. While ECHA at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

GENERAL COMMENTS FROM THE LEAD REGISTRANT

ECHA acknowledges your general comments submitted on the draft decision. ECHA acknowledges that you have an intention to update the technical dossier by August 2017 based on new available information. As described in the Appendix 2, this decision does not take into account the update after the date of when the draft decision was notified to the Registrant. The information in the updated dossier will be evaluated during the follow up process of this decision.

DEADLINE TO SUBMIT THE REQUESTED INFORMATION IN THIS 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 36 months. You sought to justify this request by providing statement from a contract research organisation that performs the requested environmental fate and ecotoxicity testing. The statement included following estimated timelines;

- the aquatic toxicity tests: 33 months assuming that long-term fish test is to be conducted after long term test with aquatic invertebrates (ITS),
- the tiered simulation tests: 24 months with additional 4 months for synthesis of the radiolabelled test substance,
- the terrestrial toxicity tests: 12 months. However taking into account the tiered testing strategy the needed time would be 24 to 30 months (aquatic toxicity) plus 12 months (terrestrial toxicity) leading to 36 to 42 months and
- the sediment toxicity test: 24 months.

ECHA notes that you have partially justified the need for extention of the deadline indicated in the decision.

- ECHA notes that there is no need to apply the ITS for aquatic studies as due to the substance properties and absence of effects in the short term tests both long term tests (Daphnia and fish) are requested without reference to ITS.
- ECHA agrees that the requested extension regarding the sequential simulation studies is acceptable. The additional time needed to synthesis of the radiolabelled substance varied from 4 to 7 months. ECHA considers that 24 months for simulation tests with additional 6 months (including the synthesis of the test substance) would be sufficient time to conduct and report the requested studies.
- The requested aquatic toxicity test are needed to be conducted first to clarify the need for long term toxicity test to terrestrial plants (12 months).
- In case the substance falls in to the soil hazard category 4 all three terrestrial tests requested should be performed. ECHAs response to the requested extension of the deadline for the aquatic toxicity testing is discussed above. For the all three requested terrestrial toxicity tests, ECHA finds acceptable the timeline of 12 months indicated by the contract laboratory (12 months + 12 months).
- In case the substance falls into the soil hazard category 3 you should first conduct the long term toxicity test with terrestrial invertebrates and soil microbes and update the CSA. If the RCRs are > 1 only then also the long term test on terrestrial plants would be needed (12 months + 9 months + 9 months).
- ECHA finds acceptable the proposed time line for the sediment toxicity test (24 months).

Therefore, ECHA has only partially granted the request and set the deadline to 30 months.

Appendix 2: Procedural history

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 8 April 2016.

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 request(s).
ECHA took into account your comments and amended the deadline.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-53 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

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

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

4. In relation to the information required by the present decision, the sample of the substance used for the new test(s) 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 test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.