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Helsinki, 14 March 2022

Addressees
Registrants of RECONSILE EC# 241-881-3 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
12/12/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1,1,1,3,5,5,5-heptamethyl-3-octyltrisiloxane
EC number: 241-881-3
CAS number: 17955-88-3

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***21 September 2023***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) by oral route, in rats

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in one species (rat or rabbit)

3. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222)

4. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

5. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species)

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH, the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Approved[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

Appendix A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted and on scientific information submitted by third parties.

1. Sub-chronic toxicity study (90-days)

A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA received third party information concerning the testing proposal during the third party consultation.

Evaluation of the third-party information

A third party has indicated that the existing OECD TG 422 study with the Substance reports a NOAEL of 1000 mg/kg bw/day and the existing OECD TG 407 study reports no treatment-related effects '*with the exception of a small number of findings due to dosing accidents*' up to 5000 mg/kg bw/day, and therefore the Substance appears to meet the definition of a 'low toxicity substance'.

ECHA understands that the third party comment refers to the adaptation possibility under Annex IX, Section 8.6.2., column 2, fourth indent. This adaptation specifies that a sub-chronic toxicity study (90-day) does not need to be conducted if "*the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day study, particularly if such a pattern is coupled with limited human exposure*". ECHA notes that all criteria need to be met.

ECHA observes that the third party comment addressed only the criterion concerning '*no evidence of toxicity*'. The third party did not submit information regarding the other cumulative criteria under Annex IX, Section 8.6.2., column 2, fourth indent.

Therefore, based on the information submitted by the third party the cumulative criteria listed in Annex IX, section 8.6.2., column 2, fourth indent are not met.

ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.6.2., column 2, fourth indent.

Considering the available information, ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

You did not specify the species to be used for testing. According to the OECD TG 408, the rat is the preferred species. Therefore, the study must be conducted in the rat.

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity (ECHA Guidance R.7a, Section R.7.5.4.3.2.).

1.3. *Outcome*

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Pre-natal developmental toxicity study in a first species

A pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

2.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

Considering the available information, ECHA agrees that a PNDT study in a first species is necessary.

2.2. Specification of the study design

You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

2.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

3. Long-term toxicity testing on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Based on the information in your registration dossier, the substance is considered as not readily biodegradable and there are no soil-specific biodegradation data on the Substance. Furthermore, based on QSAR predictions, you consider that the log Koc of the Substance is 6.

Therefore, the Substance is considered potentially highly persistent in soil and to have a high potential to adsorb to soil. On this basis information, a long-term toxicity test on terrestrial invertebrates must be provided.

3.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222) with the following justification: "*No terrestrial studies are available with the registration substance. The substance falls within soil hazard category 3 as defined in REACH R.7. As an interim approach, PNECsoil has been derived using read-across from D5. To complete the screening assessment, a confirmatory long-term soil toxicity test is required, therefore an earthworm reproduction study is planned for the registration substance*".

You have also provided an adaptation under Annex XI, Section 1.2. ('Weight of evidence'). In support of your adaptation, you provided the following sources of information:

i. a study according to OECD TG 222 on the analogue substance D5 with EC No. 208-764-9 (CAS RN 541-02-6);
ii. a study according to Environment Canada, EPS 1/RM/43 (June 2004) on the analogue substance D5 with EC No. 208-764-9 (CAS RN 541-02-6).

We have assessed the available information from your dossier on long-term toxicity to terrestrial invertebrates and identified the following issue:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

Irrespective of the above-mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information and identified the following issue:

To fulfil the information requirement, normally, a study performed according to OECD TG 222 must be provided. OECD TG 222 requires the study to investigate the following key investigations:

- mortality and growth effects on the adult worms after 4 weeks of exposure;
- effects on reproduction after a further 4 weeks by counting the number of offspring present in the soil.

The sources of information (i-ii) may provide relevant information on the key investigations of long-term toxicity to terrestrial invertebrates.

However, the reliability of these sources of information is significantly affected by the following deficiency: *The read-across approach is rejected.*

You have adapted this information requirement by applying a read-across approach in accordance with Annex XI, Section 1.5.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. Scope of the grouping

i. Description of the grouping

In your registration dossier, you have formed a group (category) of 'siloxanes'. You have provided a read-across justification document in IUCLID Section 13 entitled "*Siloxane Category Report for Environmental Endpoints*".

Your category includes 42 substances. For the purpose of this decision, the following abbreviation is used for the group member relevant for the proposed prediction for terrestrial endpoints:

[1] D5 for 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane with EC No. 208-764-9 (CAS RN 541-02-6).

You provide the following reasoning for the grouping the substances: "*The structure of the Category is associated with a consistency and predictability in the physicochemical, environmental fate, and ecotoxicological property data across its members".*

You define the applicability domain of the category as follows:

- "*The Reconsile Siloxanes Category consists of linear/branched and cyclic siloxanes (substances containing one or more Si-O-Si groups) that have been or are being registered by the* [redacted]*, or are structurally-relevant";*
- "*Siloxanes within this Category have a low functionality and a hydrolysis half-life at pH 7 and 25°C >1 hour and log Kow >4 (defined in the Reconsile Category/Analogue/QSAR overview report as sub-class I-3-3 and III-22)";*
- "*Siloxanes with reactive functional groups are excluded; in this context, reactive functional groups include hydroxyl, halogeno, alkoxy and acetoxy groups*";
- "*Substances that are identified as reaction masses are generally excluded from the Category domain, with the exception of EC number 911-381-6 (Reaction mass of*

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

2,4,6,8-Tetramethyl2,4,6,8-tetravinylcyclotetrasiloxane and 2,4,6,8,10-pentamethyl-2,4,6,8,10-pentavinylcyclopentasiloxane) which is a reaction mass of Vi4-D4 (CAS 2554-06-5) and Vi5-D5 (CAS 17704-22-2), both of which are substances falling within the Siloxane Category in their own right".

B. Predictions for terrestrial toxicity

You have provided the following reasoning for the prediction of ecotoxicity including terrestrial toxicity:

- You state that "*The OECD QSAR Toolbox was used to Profile the substances within the Category*" and "*The profiles are generally consistent across the Category. There is nothing to suggest a specific mode of action for ecotoxicity for any of the substances*";
- The category members show a consistent trend in physico-chemical properties (in particular, boiling point, vapour pressure, water solubility and n-octanol:water partition coefficient);
- The category members show similar environmental fate properties despite some differences are expected depending on structural features;
- The category members show similar lack of aquatic toxicity. You state that "*Short-term and long-term toxicity effects have been recorded with fish for L2 and D4, which are the only siloxanes in the Category to have low log Kow values. The studies with the majority of the substances indicate that no effects at the limit of solubility are detectable*".
- You consider that, in general, for the category members "*No significant toxicity (NOEC <100 mg/kg) in any organism is found at pH near 7 with natural sediment*".
- With regard toxicity on soil organisms, you state that "*The soil is considered to be a major sink for substances and is considered a complex exposure medium due to it being a three-phase matrix: non-organic and organic matter, soil pore water and pore space (soil air). In view of the high potential to adsorb to soil for the siloxane substances, and the lack of terrestrial toxicity testing across the Siloxane Category, it is concluded that a terrestrial toxicity integrated testing strategy for the Category is necessary*".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict terrestrial toxicity properties for the category members from information obtained from the following source substances:

- D5 for 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane with EC No. 208-764-9 (CAS RN 541-02-6).

ECHA notes the following shortcomings with regards to your predictions of terrestrial toxicity.

1. *Data density*

   Annex XI, Section 1.5. provides that "*substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances".*

   According to the Guidance on IRs and CSA, Section R.6.2.1.5., one of the factors in determining the robustness of a category is the density and distribution of the available data across the category. To identify a regular pattern and/or to derive reliable

prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

Furthermore, in larger categories there may be breaks in trends which could affect the reliability of interpolation (Guidance on IRs and CSA, Section R.6.2.2.2.). To confirm that there are no such breakpoints, adequate and reliable information needs to cover also substances within a range of homologous series.

You have provided terrestrial toxicity studies for a single category member (D5). You consider that a trend in terrestrial toxicity is to be expected for the category members. However, you acknowledge that "*In view of the high potential to adsorb to soil for the siloxane substances, and the lack of terrestrial toxicity testing across the Siloxane Category, it is concluded that a terrestrial toxicity integrated testing strategy for the Category is necessary*".

Information for one category member is not sufficient to establish a trend across the category consisting of 42 substances. In the absence of terrestrial toxicity data for substances across the category, it cannot be confirmed that there is no breakpoint in toxicity trend within the given range of structural features present in the category (for instance, linear, branched and cyclic siloxanes, number of Si-O-Si groups). Therefore, the information provided is not sufficient to conclude that terrestrial toxicity properties are likely to follow a regular pattern.

2. *Inadequate read-across hypothesis*

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. Firstly, this hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). Secondly, it should also explain why the differences in the chemical structures should not influence the ecotoxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

Your read-across hypothesis is only based on

- Some degree of structural similarity ("*The registered substance and the surrogate substance […] are not close structural analogues (linear and cyclic siloxanes respectively)*" and
- similarities in the physico-chemical properties of the source substance and the Substance.

You consider that these elements are a sufficient basis for predicting the (eco)toxicological properties of the Substance.

You have not substantiated how physico-chemical similarity alone would explain similarity in the predicted endpoint(s) and thus be sufficient to justify the ecotoxicological predictions.

Physico-chemical similarity alone does not necessarily lead to predictable or similar ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for an ecotoxicological property, explaining why the

structural differences do not influence toxicokinetics and toxicodynamics of the substances.

C. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Conclusion on the weight-of-evidence assessment

In conclusion, the reported information provides information on long-term toxicity to terrestrial invertebrates. However, the reliability of this information is significantly affected by the issue identified above.

As a result of these, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance shows long-term toxicity on terrestrial invertebrates as investigated in an OECD TG 222 study. Therefore, your adaptation is rejected, and the information requirement is not fulfilled.

ECHA therefore agrees that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

In the comments to the draft decision, you agree with the request.

3.2. Test selection and study specifications

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

3.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Effects on soil micro-organisms

Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

4.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (test method: EU C.21/OECD TG 216).

Your registration dossier does not include any information on effects on soil microorganisms.

ECHA agrees that an appropriate study on Soil Micro-organisms is needed.

In the comments to the draft decision, you agree with the request.

4.2. Test selection and study specifications

ECHA Guidance specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals (ECHA Guidance, Section R.7.11.3.1.).

4.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

5. Long-term toxicity to terrestrial plants

Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

As stated in Appendix A.3., the Substance is considered potentially highly persistent in soil and to have a high potential to adsorb to soil. On this basis information on long-term toxicity on terrestrial plants must be provided.

5.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (test method: OECD TG 208).

Your registration dossier does not include any information on long-term toxicity to terrestrial plants.

ECHA agrees that an appropriate study on long-term toxicity terrestrial to plants is needed.

In the comments to the draft decision, you state that the draft decision does not specify that you intend to apply a tiered testing strategy whereby the OECD TG 222 is conducted first and if there is no indication of risk from the results of the OECD TG 222 study, the OECD TG 208 study would not be conducted. You refer to a similar testing proposal decision (Decision number: TPE-D-2114422684- 49-01/F) on decamethyltetrasiloxane (L4, CAS 141-62-8, EC 205-491-7) in which ECHA acknowledges that such approach may be acceptable.

ECHA takes note that you may consider adapting this information based on the second column of Annex IX, Section 9.4. However, as your registration dossier currently does not contain such adaptation, ECHA is not in a position to assess the validity of the proposed approach.

If you decide to submit such adaptation instead of the requested study, you need to consider to what extent the available information from your dossier allows to extrapolate a $PNEC_{soil,screen}$ with sufficient reliability. ECHA further notes that the deadline set out in this decision allows for conducting the OECD TG 222 and OECD TG 208 tests sequentially.

5.2. Test selection and study specifications

The proposed Terrestrial Plant Test (test method: OECD TG 208 with a test design for long-term testing) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 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 must 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.

5.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test material must contain that constituent/ impurity.

2. Information on the Test material needed in the updated dossier
   - You must report the composition of the Test material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

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Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 February 2020.

ECHA held a third party consultation for the testing proposal(s) from 17 June 2020 until 3 August 2020. ECHA received information from third parties (see corresponding Appendix)

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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

ECHA took into account your comments and did not amend the requests.

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

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

Appendix D: List of references - ECHA Guidance[6] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.