EUROPEAN CHEMICALS AGENCY

Helsinki, 6 February 2020

Addressees
Registrant of JS_EC_451-620-7 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
30 November 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction Mass of 3,3-diphenylhexamethyltrisiloxane and 3,3,5,5-tetraphenylhexamethyltetrasiloxane
EC number: 451-620-7
CAS number: NS

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***13 November 2020***.

1. Long-term toxicity on terrestrial invertebrates (test method: earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test (OECD TG 232),) with the Substance (Annex IX, Section 9.4.1, column 2 in conjunction with Annex I, section 0.5 and Annex VI);

2. Long-term toxicity to terrestrial plants (test method: Terrestrial plant test: seedling emergence and seedling 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 Substance (Annex IX, Section 9.4.3., column 2 in conjunction with Annex I, section 0.5 and Annex VI);

3. Effects on soil micro-organisms (test method: EU C.21/OECD TG 216) with the Substance (Annex IX, Section 9.4.2., in conjunction with Annex I, section 0.5 and Annex VI).

Conditions to comply with the requests

The Appendix on general considerations addresses issues relevant for several requests while the Annex A state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

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

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 Christel Schilliger-Musset, 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 on general considerations

(i) The need for terrestrial testing

Your Substance is registered at Annex VIII of REACH. According to Article 12(1)(c) of REACH, your dossier shall therefore include as a minimum the information specified in Annexes VII and VIII. Nevertheless, according to Article 12(1) of and Annex VI to REACH, Annexes VI to XI stipulate minimum information requirements, and for each registration the precise information requirements will differ under consideration of the Annexes as a whole and the overall requirements of registration, evaluation and duty of care.

Annex VI, step 4 of the 'Guidance note on fulfilling the requirements of Annexes VI to XI' provides that the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements. Furthermore, in accordance with Annex I, certain additional information may have to be generated if it is necessary for producing the chemical safety report (CSR). According to the last subparagraph of Section 0.5. of Annex I of REACH, if the manufacturer or importer considers that further information is necessary for producing his CSR and that this information can only be obtained by performing tests in accordance with Annex IX and X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the CSR under the appropriate heading.

You have proposed to conduct the following tests on terrestrial organisms, which are not a standard information requirement at Annex VIII: Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2), Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2) and Effects on soil micro-organisms (Annex IX, Section 9.4.2.). You have justified the proposed testing by stating that "*the low water solubility, high log Kow and high log Koc of the substance indicate that it will adsorb to organic matter and partition to sludges in a waste water treatment plant*" and that "*it may be more appropriate to use terrestrial data to assess the potential toxicity of the substance in the environment*". You continue that siloxane substances have high potential to adsorb to soil.

Based on the substance properties, ECHA notes that the registered substance is highly adsorptive (log Koc of 6) and therefore, exposure and effects in soil organisms cannot be excluded. Furthermore, no risk characterisation ratio can currently be calculated using the equilibrium partitioning method and toxicity tests on aquatic organisms as no L/EC50 and consequently no $PNEC_{water}$ could be estimated during these tests. In the absence of valid risk characterization of the highly absorptive Substance, ECHA agrees that the proposed tests are necessary, within the meaning of Annex I, section 0.5 and Annex VI of REACH in order to assess the risk of the Substance to terrestrial organisms, ensure its safe use and prepare the CSR.

In addition to the testing proposals, for the endpoints of Long-term toxicity testing on invertebrates and long-term toxicity testing on plants, you have submitted studies performed on an analogue substance Decamethylcyclopentasiloxane (D5, CAS No 541-02-6, EC No 208-764-9) for the purpose of an interim hazard and risk assessment for the Substance. Under the Endpoint summary of terrestrial toxicity you note that "*The registered substance and the surrogate substance share similar physico-chemical properties but are not close structural analogues (linear and cyclic siloxanes)*".

You use the data on D5 only as "an interim hazard and risk assessment", however you have not provided any real justification as to why you consider this read-across possible, even as an interim measure. Nevertheless, ECHA notes the following.

The Substance is a multi-constituent substance containing two main constituents [redacted] The main constituent has three silicon atoms with 2 phenyl groups and 6 methyl groups while the second constituent has 4 silicon atoms, with 4 phenyl groups and 6 methyl groups. The proposed analogue substance is a cyclic siloxane with silicon atoms with methyl branches and alternated by oxygen. It is clear that the Substance and source substance are not close structural analogues. ECHA notes that in the dossier you provide no explanation on how these differences in structure affect their terrestrial toxicities. Nevertheless, you consider read-across from D5 to the Substance as acceptable based on physico-chemical similarity between the source and registered substance. However, physico-chemical similarity does not necessarily lead to predictable or similar environmental properties. Thus physico-chemical similarity per se is not sufficient to enable the prediction of environmental properties of a substance. On that basis, the requirement of Annex XI, Section 1.5., that environmental effects may be predicted from data for reference substance(s) within the group, has not been met.

Therefore ECHA concludes that the data on D5 could not be used to fulfil the current information requirement for the registered substance and terrestrial testing is needed.

(ii) Assessment of the Grouping of substances and read-across approach proposed in the testing proposals, in light of the requirements of Annex XI, Section 1.5.

You propose a testing strategy intending to fulfil the standard information requirements for:

- Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)
- Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)
- Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

In IUCLID, Sections 6.3, 6.3.1, 6.3.2 and 6.3.3 and your CSR attached to section 13 of IUCLID, you propose to test the analogue substance silsesquioxanes, phenyl, EC No. not provided (CAS No. 70131-69-0) hereafter referred to as "source substance" for the above mentioned information requirements. You propose to use the results obtained to adapt the standard information requirements for your registered Substance by using a grouping and read-across approach according to Annex XI, Section 1.5. of the REACH Regulation.

ECHA has considered the scientific and regulatory validity of your read-across approach in general before addressing the individual endpoints (Appendix A, sections 1 to 3).

Grouping of substances and read-across approach

Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by you are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal

tests, including information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*".

The first Recital and the first Article of the REACH Regulation establish the "*promotion of alternative methods for assessment of hazards of substances*" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to the present decision by using the results of the proposed tests is plausible based on the information currently available.

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.

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

A. Scope of the grouping

i. Description of the grouping

You have indicated that the Substance and the source substance are part of the category (section 6.3 of IUCLID) and provided in your dossier a read-across justification document (IUCLID Section 13) for a group (category) of "[redacted]".

Annex XI, Section 1.5 of the REACH Regulation provides that "substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."

According to the ECHA Guidance, "in identifying a category, it is important that all potential category members are described as comprehensively as possible", because the purity profile and composition can influence the overall toxicity/properties of the potential category members. Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Under section 1.2.3 of the category document you have listed the substances included in the Siloxane category. On page 19 you have provided the following exclusion criteria "*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 2,4,6,8-Tetramethyl-2,4,6,8-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.*"

You have not included the Substance in the list of the Siloxane category substances. Rather as the substance is a reaction mass it is excluded from the category approach. Therefore, the category membership cannot be confirmed.

In your comments you claim that even if the Substance is not in the list of the Siloxane

[2] ECHA Guidance R.6
[3] ECHA Read-Across Assessment Framework (RAAF)

category substances, you consider that it meets the category definition and should be considered as part of this category. You define the following as the general definition of the category: *"siloxanes with log Kow>4, half-life >1 h, containing low functionality groups, such as linear, branched or cyclic alkyl groups, hydrogen, vinyl and phenyl groups bound to the silicon"*. You also note that the exclusion criteria of reaction masses not being included with the two named exceptions is not correct as also the source substance is a reaction mass and it is listed as a substance belonging to the category.

ECHA acknowledges that both the target substance and its main constituents can fit into the category definition. However, as discussed above, this is not reflected in the category documentation in your dossier.

Furthermore, based on the justification provided in IUCLID section 6.3 and in your comments on the DD it appears that the approach proposed is rather an analogue, one-to-one read-across, approach, even if you consider that this approach is supported by data and trends across the Siloxanes Category.

In the following, ECHA examines whether the substances have indeed similar properties or that they would follow a regular pattern in their properties, before assessing the scientific validity of your hypothesis.

B. Predictions for ecotoxicological properties

You have provided the following reasoning for the prediction of (terrestrial) ecotoxicological properties, which ECHA understands forms your hypothesis of the proposed read-across: the substances are structural analogues, they have similar physicochemical properties and both have negligible biodegradability and hydrolysis rates.

In your comments on the DD you define your hypothesis further and hypothesise that the close structural similarity and similar physicochemical properties, absence of reactive groups and similar mode of action, non-polar narcosis, lead to similar toxicity of the Substance and the source.

ECHA notes the following shortcomings with regards to prediction of ecotoxicological properties.

i. *Relevance of the supporting information*

According to the ECHA Guidance[4] *"it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals"*.

In order to support your claim that your Substance and the source substance have similar properties for the endpoints under consideration in the read-across approach, you refer to their environment fate properties by stating that *"both have negligible biodegradability and hydrolysis rates"*. You have also provided the Log Koc values for both the source and the Substance. You have provided the hydrolysis rates (the Substance: >200 h of constituent 1, > 630 h of constituent 2, the source substance 630 to > 63 000 h) but provide no further information on the ready biodegradation study on the source.

[4] ECHA Guidance R.6, Section R.6.2.2.1.f

Whilst information on hydrolysis may inform on the environmental fate and behaviour of substances in aquatic environments it does not inform on the degradation and behaviour of the Substance and the source substance in terrestrial environments. Furthermore, the rates provided are such that hydrolysis is not a relevant variable considering the fate of the two substances.

In your comments on the DD you agree that due to the high adsorption potential of both substances terrestrial organisms would be exposed to the parent substances and hydrolysis may not occur.

You claim that both substances have negligible biodegradability, but do not provide any data to substantiate your claim.

In your comments on the DD you acknowledge that neither substance has data on biodegradation in soil and that there is no ready biodegradation study available on the source substance. You indicate that based on review of data in the siloxanes category the category substances are in general not readily biodegradable.

You base your conclusion on negligible biodegradation on data obtained across the Siloxanes Category. The Category includes substances of varying structures as substances "*containing low functionality groups, such as linear, branched or cyclic alkyl groups, hydrogen, vinyl and phenyl groups bound to the silicon*" and properties "*siloxanes with log Kow>4, half-life >1 h*" are included. The category boundaries are wide. You have not provided a well-founded hypothesis to establish a reliable prediction for biodegradation, based on recognition of the variety of structural and physicochemical similarities and differences between the source substance(s) and your Substance neither in your comments on the DD nor in the category document attached to IUCLID.

You consider that the substances' stability and behaviour in soil is linked to their Log Koc values (similar), the biotic and abiotic degradation of neither substance in soil is a significant process to consider. Consequently you consider both substances to have similar fate in soil.

ECHA agrees that based on their adsorption potential the substances may behave similarly in soil, however you have no ready biodegradation nor soil degradation data to support your hypothesis of similar fate, especially in the target compartment soil. Accordingly, the information provided is not alone considered as relevant to support the prediction of the terrestrial endpoints under consideration.

iii. Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[4]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

As indicated above, your read-across hypothesis appears to be based on the assumption that the structurally and physico-chemically similar substances cause the same type of effects. In this context, relevant, reliable and adequate information allowing to compare the

properties of the Substance and of the source substance is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance.

In your comments on the DD you indicate that new long-term aquatic invertebrate toxicity data with the source substance has become available and you can now compare it with the short-term data available with the Substance.

In order to compare the aquatic toxicity data the studies would need to be of comparable design, especially equivalent duration and address comparable trophic levels. The data obtained must also be meaningful for the purpose. Poorly water soluble substances require longer time to reach steady-state conditions and short-term tests may not give a true measure of toxicity for this type of substances.

Both the target and the source substances are poorly water soluble. Also, you have reported the source data but have not provided the study. For the Substance there is only short-term aquatic data available.

Due to poor water solubility the short-term data is meaningless to compare and decide on the toxic potential of the Substance. The information provided is not considered as relevant to support the prediction of the terrestrial endpoints under consideration.

There currently is no terrestrial toxicity data available on either of the substances. In your comments, you report that "*No or low toxicity have been observed with linear and cyclic siloxanes*" and that further terrestrial toxicity data showing similar results is being developed.

You expect the Substance and the source to have similar terrestrial toxicity based on data obtained across the Siloxanes Category. The Category includes substances of varying structures as substances "*containing low functionality groups, such as linear, branched or cyclic alkyl groups, hydrogen, vinyl and phenyl groups bound to the silicon*" and properties "*siloxanes with log Kow>4, half-life >1 h*" are included. The category boundaries are wide. You have not provided a well-founded hypothesis to establish a reliable prediction for terrestrial toxicity, based on recognition of the variety of structural and physicochemical similarities and differences between the source substance(s) and your Substance neither in your comments on the DD nor in the category document attached to IUCLID.

In the absence of such information, you have not established that the Substance and the source substance are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

C. Conclusions on the read-across approach

Based on the above considerations ECHA concludes that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoints in consideration. ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are not met, and consequently the testing proposed on the source substance is not appropriate to fulfil the information requirements of the substance subject to the present decision.

EUROPEAN CHEMICALS AGENCY

Appendix A: Reasons for the requirements

This decision is based on the examination of the testing proposals you submitted.

1. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2 in conjunction with Annex I, section 0.5 and Annex VI)**

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing on terrestrial invertebrates must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD TG 222) to be performed with the analogue substance Silsesquioxanes, phenyl (CAS No 70131-69-0).

The Substance has a high potential to adsorb to soil (log Koc 6) and is potentially very persistent (default setting for non-readily biodegradable substances when half-life in soil is not available, Section R.7.11.5.3 of ECHA Guidance R.7c).

As discussed in the Appendix on general considerations, section (i) you have indicated a need to generate this information. ECHA agrees that testing on terrestrial invertebrates is necessary, within the meaning of Annex I, section 0.5 and Annex VI of REACH in order to assess the risk of the Substance to terrestrial organisms, ensure its safe use and prepare the CSR.

ECHA has evaluated your proposal to perform the test with the analogue substance Silsesquioxanes, phenyl. As explained in the Appendix on general considerations, section (ii), your adaptation according to Annex XI, Section 1.5 is rejected, and therefore your proposal to test the analogue substance, Silsesquioxanes, phenyl, is also rejected according to Article 40(3)(d).

The earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) are considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates, also for the highly adsorptive substances with the log Kow above 5, such as the Substance.

According to Article 40(3)(c) of the REACH Regulation, you are requested to carry out one of the tests indicated above with the Substance.

2. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2 in conjunction with Annex I, section 0.5 and Annex VI)**

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH. Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing on terrestrial plants must be considered instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

You have submitted a testing proposal for a long-term toxicity test to terrestrial plants (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test, OECD TG 208) to be performed with the analogue substance Silsesquioxanes, phenyl (CAS No 70131-69-0).

The Substance has a high potential to adsorb to soil (log Koc 6) and is potentially very persistent (default setting for non-readily biodegradable substances when half-life in soil is not available, Section R.7.11.5.3 of ECHA Guidance R.7c).

As discussed in the Appendix on general considerations, section (i) you have indicated a need to generate this information. ECHA agrees that testing on terrestrial plants is necessary, within the meaning of Annex I, section 0.5 and Annex VI of REACH in order to assess the risk of the Substance to terrestrial organisms, ensure its safe use and prepare the CSR.

ECHA has evaluated your proposal to perform the test with the analogue substance Silsesquioxanes, phenyl. As explained in the Appendix on general considerations, your adaptation according to Annex XI, Section 1.5 is rejected, and therefore your proposal to test the analogue substance, Silsesquioxanes, phenyl, is also rejected according to Article 40(3)(d).

You have indicated that you would first carry out a long-term terrestrial invertebrate study (request A.1) and in case of risks observed you would conduct the long-term plant study. You have justified that strategy by claiming that your Substance can be allocated to soil hazard category 3.

ECHA considers that the need for long-term plant testing cannot be decided upon the results of test requested in A.1. and the test for the long-term plant has to be performed anyway. Specifically, to be able to assign the substance to an appropriate soil hazard category and to apply the screening assessment through the use of the EPM approach (in accordance with Column 2 of Annex IX, section 9.4.) there has to be adequate data for a reliable $PNEC_{water}$ (ECHA Guidance R.7c, section R.7.11.6 and table R7.11-2).

As discussed in point (i) of the in the Appendix on general considerations it has not been possible to derive a $PNEC_{water}$. Therefore, accurate allocation of an appropriate soil hazard category according to table R7.11-2 of the abovementioned guidance, is not possible and the need for long-term plant testing does not depend on the results of the invertebrate testing. The proposed test on terrestrial plants (OECD TG 208) is appropriate to fulfil the information requirement of Annex IX, Section 9.4.3. OECD 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 208 guideline.

According to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the test with the Substance.

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2. in conjunction with Annex I, section 0.5 and Annex VI)

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4. to REACH.

You have submitted a testing proposal for soil micro-organisms test (Soil Microorganisms: Nitrogen Transformation Test, OECD TG 216) to be performed with the analogue substance Silsesquioxanes, phenyl (CAS No 70131-69-0).

As discussed in the Appendix on general considerations you have indicated a need to generate this information. ECHA agrees that testing on soil micro-organisms is necessary, within the meaning of Annex I, section 0.5 and Annex VI of REACH in order to assess the risk of the Substance to terrestrial organisms, ensure its safe use and prepare the CSR.

ECHA has evaluated your proposal to perform the test with the analogue substance Silsesquioxanes, phenyl. As explained in the Appendix on general considerations, your adaptation according to Annex XI, Section 1.5 is rejected, and therefore your proposal to test the analogue substance, Silsesquioxanes, phenyl, is also rejected according to Article 40(3)(d).

According to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the test with the Substance.

Appendix E: Procedural history

ECHA received your registration containing the testing proposals for examination on 4 December 2018.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the request(s).

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix B: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

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

3. Test guidelines, GLP requirements and reporting

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

   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.

   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: 'How to report robust study summaries'[5].

4. Test material

   Selection of the test material(s)

   While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[6].

5. List of references of the ECHA Guidance and other guidance/ reference documents[7]

   QSARs, read-across and grouping

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals
[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[8]

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.

OECD Guidance documents
Guidance Document on aqueous –phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.

[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Appendix C: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number
[redacted]	[redacted]