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Helsinki, 22 February 2022

**Addressees**
Registrant of Reaction mass 904-153-2 listed in the last Appendix of this decision

**Date of submission of the dossier subject of a decision**
29/10/2020

**Registered substance subject to this decision, hereafter 'the Substance'**
Substance name: Reaction mass of propylidynetrimethanol and 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol
List number: 904-153-2
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 TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***29 February 2024***.

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. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

### B. Information required from the Registrants subject to Annex X of REACH

1. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) by oral route, in rats, specified as follows:

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

2. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: OECD TG 218 or TG 225 or TG 233)

Reasons for the requests are explained in the following appendices entitled "Reasons to request information required under Annexes IX to X of REACH", respectively.

**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 to X to REACH, for registration at more than 1000 tpa.

**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". 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.

## 1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

### *1.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211).

You have also provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: *"In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex IX, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment."*

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

### *1.2.* Test selection and study specifications

The proposed *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

### *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.

In your comments to the draft decision, you agree to conduct the requested OECD TG 211 study on the Substance.

## 2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of

the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. In case of data gap for long-term toxicity testing on fish, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

*2.1. Information provided to fulfil the information requirement*

You have provided the following information: a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "Long-term toxicity testing to fish was not considered to be necessary since there was no toxicity to fish observed in the available acute tests and there was no evidence from the available data that fish are more sensitive compared to aquatic invertebrates or algae. Thus, in order to avoid unnecessary vertebrate testing, no additional long-term test with fish was proposed."

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

*2.2. Test selection and study specifications*

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

*2.3. Outcome*

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

In your comments on the draft decision, you refer to Section 9.1, Column 2 of Annex IX and state that "*long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the effects on aquatic organisms and that the choice of the appropriate test(s) depends on the results of the chemical safety assessment.* Therefore, you propose to follow an iterative process instead of testing the long-term toxicity in fish directly. You state that "[u]*nder consideration of animal welfare reasons and to avoid unnecessary testing in vertebrates, the long-term toxicity study in fish according to OECD guideline 210 will only be conducted if the CSA indicates a further need for testing*".

ECHA has assessed this information from your comments on the draft decision and identified the following issue:

As already explained above, Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. A registrant may only adapt this information requirement based on the general rules set out in Annex XI The

minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

Therefore, an adaptation based on Annex IX, Section 9.1., Column 2 cannot be regarded as a valid basis to omit this information requirement.

## 3. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

Simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable (Annex IX, Section 9.2.1.2, column 2).

The information provided in your dossier indicates that:

- the Substance is well soluble (water solubility limit of c.a. 1000 g/L based on OECD TG 105)
- You concluded that the Substance is not readily biodegradable because some constituents (TMP) are only regarded as inherently biodegradable.

Therefore, the Substance is considered to be well soluble and not readily biodegradable and information on Simulation testing on ultimate degradation in surface water must be provided.

### *3.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for an Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: OECD TG 309).

You have also provided the following justification to omit this information: "In accordance with REACH Annex XI, based on available data, the substance is not classified as hazardous for the environment. Therefore, degradation simulation testing in water and/or sediment does not need to be conducted."

We have assessed this information and identified the following issue:

> A registrant may only adapt this information requirement based on the specific rules set out under Annex IX, Section 9.2.1.2 column 2 or the general rules set out in Annex XI to REACH.
>
> Your justification to omit this information does not refer to any legal ground for adaptation under Annex IX, Section 9.2.1.2 column 2 or Annex XI.

Therefore, you have not demonstrated that this information can be omitted.

On this basis, the information requirement is not fulfilled.

Therefore, ECHA agrees that an appropriate simulation study on ultimate degradation in surface water is needed.

### *3.2. Test selection and study specifications*

The proposed Aerobic mineralisation in Surface Water – Simulation biodegradation test (test method: OECD TG 309) is appropriate to cover the information requirement for degradation/biodegradation (ECHA Guidance R.7.9.4.1).

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1.).

### *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.

In your comments to the draft decision, you explain that the Substance is a multi-constituent substance composed of three main constituents CTF (CAS 5187-23-5), TMP (CAS 77-99-6) and DMP (CAS 2612-29-5). CTF and DMP were found to be readily biodegradable in studies conducted according to OECD TG 301A while TMP was found to be inherently biodegradable (ca. 99 % after 28 days; pass level (70%) achieved after 3 days) based on OECD TG 302B. The corresponding studies are already included in your registration dossier. On the Substance, you acknowledge that:

- the Substance contains impurities with unknown biodegradability;
- the Substance cannot be considered readily biodegradable based on currently available data.

However, you consider that the available information indicates a high degree of biodegradability of the Substance. Therefore, you intend to conduct first a new ready biodegradability study. If the Substance is shown to be readily biodegradable, you intend to

adapt this information requirement under Annex IX, Section 9.2.1.2., column 2. If this is not the case, you agreed to conduct the requested study.

As the new ready biodegradability study, referred in your comments, is not available yet, ECHA cannot evaluate the validity of the proposed adaptation. Further, ECHA emphasizes that the revised introduction to the OECD Guidelines for Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. which are composed of constituents expected to show similar degradation kinetics). However, such tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For complex substances, a single ready biodegradability test may not allow to conclude on the ready biodegradability of all constituents and relevant impurities.

## 4. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal only for a simulation testing on ultimate degradation in surface water. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

### *4.1. Information needed to fulfil the information requirement*

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, the information requirement is not fulfilled, and an identification of degradation products is needed.

### *4.2. Specification of the study design*

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log $K_{ow}$ and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendix A.3. or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Appendix A.3.) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

### *4.3. Outcome*

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Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

In your comments to the draft decision, you provided the same comments as those already addressed above under Appendix A.3. As already explained, as the new ready biodegradability study you are referring to is not yet available, ECHA cannot evaluate the validity of the proposed adaptation.

## Appendix B: Reasons to request information required under Annex X of REACH

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

### 1. Extended one-generation reproductive toxicity study

The basic test design of an extended one-generation reproductive toxicity study (EOGRTS) is a standard information requirement under Annex X to the REACH Regulation. Furthermore, column 2 of Section 8.7.3. defines when the study design needs to be expanded.

#### *1.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for an EOGRTS according to OECD TG 443 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Toxicity to reproduction. 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 agrees that an EOGRTS is necessary.

#### *1.2. Specification of the study design*

*Species and route selection*

You did not specify the species to be used for testing for testing. According to the test method OECD TG 443, the rat is the preferred species. Therefore, the study must be conducted in the rat.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration, since the Substance to be tested is a liquid.

*Pre-mating exposure duration and dose-level setting*

You proposed ten weeks pre-mating exposure duration. ECHA agrees with your proposal. Ten weeks pre-mating exposure duration is required because there is no substance specific information in the dossier supporting shorter pre-mating exposure duration (ECHA Guidance R.7a, Appendix R.7.6-3).

In order to be compliant and not to be rejected due to too low dose levels, the highest dose level must aim to induce systemic toxicity, but not death or severe suffering of the animals, to allow comparison of reproductive toxicity and systemic toxicity. The dose level selection should be based upon the fertility effects, with the other cohorts being tested at the same dose levels. A descending sequence of dose levels should be selected in order to demonstrate any dose-related effect and to establish NOAELs.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a range-finding study (or range finding studies) are reported with the main study.

You must provide a justification with your study report that demonstrate that the dose level selection meets the conditions described above.

The data gap for sexual function and fertility remains despite of the newly provided Pre-natal developmental toxicity studies. Even if the classification as toxic for reproduction category 1B for developmental toxicity would be warranted based on the new information, testing for effects on fertility is still justified.

*Cohorts 1A and 1B*

Cohorts 1A and 1B belong to the basic study design and shall be included.

### *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.

*Further expansion of the study design*
The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX/X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in ECHA Guidance R.7a, Section R.7.6.

In your comments to the draft decision, you agree to conduct the requested OECD TG 443 study on the Substance.

## 2. Long-term toxicity testing to sediment organisms

Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.).

### *2.1. Information provided to fulfil the information requirement*

You have submitted a testing proposal for a Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218)

Your dossier does not include any information on long-term toxicity to sediment organisms.

Therefore, ECHA agrees that an appropriate study on long-term toxicity to sediment is needed.

### *2.2.* Test selection and study specifications

The Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218 or 233), the Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment (test method: OECD TG 225) and the Water-Sediment *Myriophyllum Spicatum* Toxicity Test (test method: OECD TG 239) are most relevant when generating new data for REACH purposes (ECHA Guidance R.7.8.9.1.).

For strongly adsorbing or binding substances (e.g. log Kow > 5) sediment-dwelling organisms that feed on sediment particles (e.g. *Lumbriculus variegatus*, *Tubifex tubifex*) are considered

of particular relevance. However, if a specific mode of action cannot be excluded other species may also provide useful information (ECHA Guidance R.7.8.10.1).

For substances that have an equilibration time (time to reach steady state in the body) that is anticipated to be very long (e.g. highly lipophilic substance such as substance with Kow > 5), studies with longer test duration are preferred. For such substance, the Sediment-water chironomid life-cycle test using spiked water or spiked sediment (test method: OECD TG 233), which is an extension of the Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218), is preferred (ECHA Guidance R.7.8.9.1. and R.7.8.14.2.). Furthermore, the OECD TG 233 specifies, that when testing strongly adsorbing substances (typically with log Kow > 5), the test material must be added to the formulated sediment before the stabilisation period.

*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.

In your comments on the draft decision, you refer to Section 9.5.1, Column 2 of Annex X and state that "*long-term toxicity testing shall be proposed by the registrant if the Chemical Safety Assessment indicates the need to investigate further the effects of the substance and/or its degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the Chemical Safety Assessment".* You further state that "[i]*nstead of testing the long-term toxicity in sediment organisms directly, the exposure and risk assessment will be re-evaluated after availability of the results of the long-term toxicity testing on aquatic invertebrates"*. The long-term toxicity study in sediment organisms according to OECD guideline 218, 225, or 233 will only be conducted if the CSA indicates a further need for testing.

ECHA notes that you have not provided an exposure assessment allowing to compare predicted environmental concentrations (PECs) to the reported predicted no effect concentrations (PNEC) for the sediment compartment. Without this information your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled for the sediment compartment. Currently, a $PNEC_{sediment,screen}$ cannot be extrapolated using the Equilibrium partitioning method (EPM) as no effects have been reported in the aquatic studies available in your dossier and you do not yet have the results of the long-term aquatic studies in Appendices A.1 and A.2.

ECHA notes that the data required to justify such adaptation is not yet available. Therefore, at this stage, ECHA cannot assess your proposal.

## Appendix C: 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[2].

### B. Test material

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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

## Appendix D: General recommendations when conducting and reporting new tests for REACH purposes

### A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.

**Appendix E: Procedure**

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 18 November 2020.

ECHA held a third party consultation for the testing proposal(s) from 18 February 2021 until 5 April 2021. ECHA did not receive information from third parties.

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 adopted the decision under Article 51(3) of REACH.

**Appendix F: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[7]
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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

## Appendix G: 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.