~~Confidential~~

Helsinki, 20 January 2022

Addressees
Registrants of DEA Polyborate_701-083-2 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
05/01/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction products of orthoboric acid with 2,2'-iminodiethanol (1:1)
EC number: 701-083-2
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 ***27 July 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 aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211) with the Substance

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

5. Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: EU C.8./OECD TG 207), or Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: OECD TG 222)

6. Short-term toxicity on terrestrial plants (Annex IX, Section 9.4.3; test method: EU C.31./OECD TG 208, with at least three species)

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

Your originally proposed tests using an analogue substance 'Reaction products of monoethanolamine and boric acid (1:1), EC No 701-025-6' are rejected, according to Article 40(3)(d):

- Sub-chronic toxicity study (90-day), oral route (EU B.26./OECD TG 408)
- Pre-natal developmental toxicity study (EU B.31./OECD TG 414)
- Long-term toxicity testing on aquatic invertebrates (EU C.20./OECD TG 211)
- Long-term toxicity testing on terrestrial invertebrates (OECD TG 222)
- Toxicity to terrestrial plants (OECD TG 227)
- Effects on soil micro-organisms (EU C.21./OECD TG 216 and EU C.22./ OECD TG 217))

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annexes IX 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, 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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2)
- Short-term toxicity to terrestrial plants (Annex IX, Section 9.4.3)
- Effects on soil micro-organisms (Annex IX, Section 9.4.2)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

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, 4].

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You propose to read-across between the substance Reaction products of monoethanolamine and boric acid (1:1), (MEA polyborate; EC No 701-025-6), as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties: *"DEA polyborate is very similar to MEA Polyborate, differing only in the use of diethanolamine (EC number 203-868-0, CAS number 111-42-2) instead of monoethanolamine.".*

Furthermore, you state that *"the differences between MEA Polyborate and DEA polyborate fall into two categories. Firstly, the additional hydroxyl group provides a further site for esterification. Since the alkanolamine is only partially esterified anyway, this has little impact on the final alkanolamine borate. Secondly, the higher MW would mean that the alkanolamine moiety in all of the constituent substances in the alkanolamine borate would be of a slightly higher MW in the DEA polyborate than in the MEA Polyborate. This would have minimal effect on the toxicological profile other than in these two areas:*

(i) *The higher average MW would be expected to reduce the exposure to the test*

[2] ECHA Guidance R.6: QSARs and grouping of Chemicals. 2008
[3] Read-Across Assessment Framework (RAAF). 2017 (March)
[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017

substance from dermal exposure. As a rule of thumb, higher MW substances move more slowly across dermal tissue.

(ii) *The presence of a different alkaline moiety could impact pH value. This could in turn affect the irritancy of the substance. As a weaker base, DEA has a lower pH than that of MEA in solution. The pKa values of MEA and DEA are 9.5 and 8.9 respectively. Salts and other compounds of DEA would also be expected to have a lower pH and irritancy potential than corresponding salts and compounds of MEA. It therefore follows that DEA polyborate would be expected to have lower irritancy than MEA polyborate, and MEA polyborate is itself not classified for any irritation effects."*

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.

ECHA notes the following shortcoming with regards to predictions of toxicological properties.

Missing information on the impact of non-common compounds

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*"[5]. 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).

Supporting information must include information on the impact of exposure non-common compounds on the prediction. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s), with the source and the target substances being reaction products of MEA or DEA with boric acid, respectively. In this context, exposure to the Substance and of the source substance may also lead to exposure to other compounds than the common compound of interest. The impact of the non-common compounds on the prediction of properties of the target needs to be assessed to ensure that a reliable prediction can be made.

In your registration dossier, under the toxicokinetics section you indicate that "*The toxicokinetic behaviour of DEA Polyborate at concentrations after ingestion will be similar to other borates*.". Therefore, while the toxicokinetic information is not available for the Substance or the source substance, it is reasonable to assume, without information to show otherwise, that following ingestion the substances can hydrolyse to the primary acid (boric acid) and alcohol - DEA in the Substance and MEA in the source substance.

For human health properties, you conclude that the presence of different alkaline moiety could impact the pH value and thereby irritancy potency of the Substance. In addition, you have provided comparable acute toxicity data in rats showing low acute toxicity via dermal route for the source substance and the Substance.

[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

Following treatment with the Substance and the source substance, exposure to DEA and MEA, respectively, are expected. However, the toxicity profiles of the DEA and MEA are different. While both substances have harmonised classifications for acute toxicity and local effects (corrosion/irritation), DEA is also classified as STOT RE 2 with the hazard statement 'May cause damage to organs through prolonged or repeated exposure'. The reported target organs of DEA following systemic exposure include, but are not limited to blood, kidney, liver, testis, brain and spinal cord (IARC monograph 101). Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is suspected of damaging fertility or the unborn child (Repro 2).

You have considered the impact of different alkaline moiety on the local irritating potential and provided bridging information related to acute dermal toxicity. However, you have failed to consider the impact of structural differences and potential exposure on non-common compounds on the systemic toxicity following repeated exposure to the substances.

Therefore, you have not provided adequate and reliable information addressing the impact of the non-common compounds DEA and MEA resulting from repeated exposure to the Substance and the source substance. In the absence of such information, you have not established that a reliable prediction of the property under consideration of the Substance can be derived on the basis of your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

B. Predictions for ecotoxicological properties

You have provided no reasoning for the prediction of aquatic and terrestrial toxicity. In your testing proposals you propose to read-across between the substance Reaction products of monoethanolamine and boric acid (1:1), EC No 701-025-6 as source substance and the Substance as target substance.

As for toxicological properties, ECHA understands that you intend to predict the ecotoxicological 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.

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

Absence of ecotoxicologial read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[6]

You have provided testing proposals to conduct aquatic and terrestrial toxicity studies with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this ecotoxicological information is relevant for your Substance, as the documentation provided in your technical dossier only covers the predictions for toxicological properties.

In the absence of such documentation, ECHA cannot verify that the ecotoxicological properties of your Substance can be predicted from the data on the source substance(s).

[6] ECHA Guidance R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

Supporting ecotoxicological 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*"[7]. 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).

"Supporting information must include bridging studies to compare properties of the Substance and source substances."

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) 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(s).

The ecotoxicological data set reported in the technical dossier includes only one fish short-term toxicity study on the Substance (EC 701-083-2). There are no studies available in the technical dossier on the source substance (EC No 701-025-6) that is indicated as a test substance to be used in your testing proposal. Furthermore, the data set reported in the technical dossier does not contain any terrestrial toxicity data on the Substance or either of the source substance(s).

Based on above, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

In the absence of such information, you have not established that the Substance and the source substance(s) 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

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.

[7] ECHA Guidance R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

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. 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 analogue substance Reaction products of monoethanolamine and boric acid (1:1) (EC No 701-025-6).

ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA agrees that a 90-day study is necessary.

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. Specification of the study design

According to the OECD TG 408, the rat is the preferred species. Therefore, the study must be conducted in the rat.

The oral route of administration is the first choice for investigating systemic toxicity (ECHA Guidance R.7a, Section R.7.5.4.3.2.).

1.4. *Outcome*

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.

2. Pre-natal developmental toxicity study

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.).

1.1. 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 and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA agrees that a PNDT study in a first species is necessary.

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. Specification of the study design

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.).

The oral route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

1.4. Outcome

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.

3. 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) with the analogue substance Reaction products of monoethanolamine and boric acid (1:1) (EC No 701-025-6).

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

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

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. 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.).

1.4. Outcome

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.

4. 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.

1.1. Information provided to fulfil the information requirement

You have omitted this information and you provided the following justification: "*Daphnia test to be carried out on related substance for read across.*"

We have assessed this information and identified the following issue:

A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, cannot be used as a basis for omitting the need to submit information on long-term toxicity to fish under Column 1 (see for example, Decision of the Board of Appeal in case A-011-2018).

Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

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

On this basis, the information requirement is not fulfilled.

1.2. 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.).

1.3. Outcome

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

5. Short-term or long-term toxicity to 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 (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

1.1. 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 analogue substance Reaction products of monoethanolamine and boric acid (1:1) (EC No 701-025-6).

Your registration dossier does not include any information on short-term or long-term toxicity on terrestrial invertebrates.

ECHA agrees that an appropriate study on toxicity to terrestrial invertebrates is needed. A short-term study on terrestrial invertebrates is a standard information requirement under column 1 of Annex IX, Section 9.4.1.

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. Test selection and study specifications

The earthworm acute toxicity test (test method: EU.C.8/OECD TG 207) is appropriate to cover the information requirement for short-term toxicity to invertebrates.

The proposed Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD TG 222 is appropriate to cover the information requirement for long-term toxicity to invertebrates (ECHA Guidance R.7.11.3.1.). Such test can also cover the information requirement for short-term toxicity to invertebrates.

You may therefore choose to perform one of these tests to address the information requirement.

1.4. Outcome

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out one of the tests specified above with the Substance.

6. Short-term toxicity on terrestrial plants

Short-term toxicity to plants is an information requirement under Annex IX to REACH (Section 9.4.3.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Terrestrial Plant Test: Vegetative Vigour Test (test method: OECD TG 227) with the analogue substance Reaction products of monoethanolamine and boric acid (1:1) (EC No 701-025-6) without any justification.

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

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

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. Test selection and study specifications

The proposed Vegetative Vigour Test (test method: OECD TG 227) is appropriate to cover the information requirement for short-term toxicity to plants for the substance that causes plant exposure via deposition on the leaves and above-ground portions of plants (ECHA Guidance R.7.11.3.1.). Uses causing such plant exposure, e.g. direct spraying, are not reported for your substance and the proposed OECD TG 227 test is therefore not considered appropriate.

Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) is appropriate to cover the information requirement for short-term toxicity on terrestrial plants for industrial substances, such as your substance, that are likely to be applied via sewage sludge (ECHA Guidance R.7.11.3.1.).

1.4. Outcome

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional tests with the Substance, as specified above.

7. Effects on soil micro-organisms

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

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) and Carbon Transformation Test (EU C.22/OECD TG 217) with the analogue substance Reaction products of monoethanolamine and boric acid (1:1) (EC No 701-025-6).

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

ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

1.2. Grouping of substances and read-across approach

As explained in the Appendix on Reasons common to several requests, your proposed read-across adaptation is rejected.

1.3. Test selection and study specifications

The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) and Carbon Transformation Test (EU C.22/OECD TG 217) are appropriate to cover the information requirement on effects on soil microorganisms for the substance that has agrochemical uses with direct application to soil (ECHA Guidance R.7.11.3.1.). ECHA Guidance R.7.11.3.1. further 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. As no agrochemical uses are reported for your substance, the proposed Nitrogen Transformation Test (EU C.21/OECD TG 216) is sufficient to cover the information requirement and the proposed Carbon Transformation Test (EU C.22/OECD TG 217) test is not considered necessary.

1.4. Outcome

Your testing proposal is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional tests 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[8].

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:

a) 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

a) 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.

b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that detailed information, ECHA can confirm 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[9].

[8] https://echa.europa.eu/practical-guides
[9] https://echa.europa.eu/manuals

Appendix C: 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 D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 15 January 2018, following the necessary clarification of the identity of your substance.

ECHA held a third party consultation for the testing proposal(s) from 27 January 2020 until 12 March 2020. 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 did not receive any comments within the commenting period.

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 E: List of references - ECHA Guidance[10] 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)[11]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[12]

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.

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

OECD Guidance documents[13]
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.

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

Appendix F: 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.