~~Confidential~~

Helsinki, 13 April 2022

Addressees
Registrant(s) of EC_942-022-1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
20/03/2019

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of hexadecane-1,2-diol and octadecane-1,2-diol
EC number: 942-022-1

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***19 July 2023***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. B/C/D/F/OECD TG 301/B/C/D/F or EU C.29./OECD TG 310)

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal
This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply
If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

1.1. Information provided

2 You have provided a short-term (OECD TG 202) study but no information on long-term toxicity on aquatic invertebrates for the Substance.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issues:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

4 In the provided OECD TG 105 (2012) study, the saturation concentration of the Substance in water was determined to be 300 µg/L.

5 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

1.3. Study design and test specifications

6 The Substance is difficult to test due to the low water solubility (0.3 mg/L) and adsorptive properties (Log Kow 4.67-5.51). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

7 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

8 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most

constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

2. Growth inhibition study aquatic plants

9 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

10 You have adapted this information requirement by using a Grouping of substances and read-across approach and provided the following information:

(i) A key study performed according to OECD TG 201 with the source substance SP4834-TS12007 (Named as Substance A in the justification document), CAS No. 1384165-12-1 ([redacted]; 2013).

(ii) Read-across justification document in IUCLID Section 6.1.5.

11 You provide the following reasoning for the prediction of this information requirement: "The data from structural analogues can be used to predict toxicological outcomes based on structural similarities between analogue compounds [i.e. Substance A] and the Notified Substance (e.g., functional groups, chemical class). Thus, for the Notified Substance, the read-across approach is used for the algae toxicity test data".

12 Further you add the following: "SUBSTANCE A is a mixture of C18 alkyl chain length borated ester, C18 oligomers of the borated ester, and borated ethers. SUBSTANCE A will hydrolyze rapidly and completely upon contact with water ([redacted] 2013), resulting in the borated esters breaking down into boric acid and two components of the Notified Substance: 1,2-octadecanediol and polyethers".

13 You also mention that "The Notified Substance is not expected to cause toxicity to freshwater algae. This is based on read-across justification with a structural analogue, SUBSTANCE A".

14 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

2.2. Assessment of the information provided

15 We have assessed this information and identified the following issue(s):

2.2.1. Read-across adaptation rejected

16 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 Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

17 We have identified the following issue(s) with the prediction of ecotoxicological properties:

2.2.1.1. Missing of supporting information

18 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" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). 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).

19 Supporting information must include supporting information to compare properties of the Substance and source substances.

20 Missing information on the formation of common compound

21 As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, information characterising the rate and extent of the (bio)transformation of the Substance and of the source substance(s) is necessary to confirm the formation of the proposed common (bio)transformation product and to assess the impact of the exposure to the parent compounds

In your read-across justification document you indicate that the source substance i.e. substance A will hydrolyse rapidly and completely in water resulting in the borated esters breaking down into boric acid and two components of the Substance. However, you have not provided any experimental information, about the (bio)transformation (i.e. Hydrolysis data) of source substance to support your claims regarding formation of common compounds and to assess the impact of exposure to non-common compounds.

In the absence of this information, you have not provided supporting evidence establishing that the proposed common (bio)transformation product is formed as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

22 Missing information on the hazards of the constituents

23 Furthermore, in your justification document you specify that the source substance (i.e. substance A) will hydrolyse into boric acid and two components of the Substance: 1,2-octadecanediol and polyethers. You have also mentioned the presence of [redacted] constituent (i.e. [redacted] with a concentration of [redacted]%) in the Substance that is not present in the source substance. However no hazard data and no justification is provided in your dossier for this constituent (i.e. [redacted]).

24 Regarding the source study, besides the specific reasons why this study cannot be considered reliable are explained further below under Section 2.2.1.2 of this Appendix, the study was performed with the source substance (i.e. substance A) addressing only the properties of two main constituents of the Substance (i.e. [redacted]). However it does not address the properties of the other constituent (i.e. [redacted]). In the absence of information for the other constituent of the Substance no reliable conclusions on the hazardous properties of the Substance as a whole can be derived. Thus

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

25 Due to the above, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

2.2.1.2. Adequacy and reliability of study on the source substance

26 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 201, and meet the requirements of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

27 Reporting of the methodology and results

a) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

28 Additional requirements applicable to difficult to test substances

b) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
   1) an analytical method validation report demonstrating that the analytical method is appropriate, and
   2) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;
   3) a justification for, or validation of, the separation technique is provided especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix.

29 Your registration dossier provides a study according to OECD TG 201 showing the following:

30 Reporting of the methodology and results

a) on the analytical method adequate information, i.e. performance parameters of the method e.g. LOQ, LOD is not reported. The results of the analytically determined exposure concentrations are not provided;

31 Additional requirements applicable to difficult to test substances

b) On analytical method, no validation of the analytical method is provided, only information that the test material concentration was determined based on boron content detected through ICP-MS. Furthermore, on the preliminary solubility study, the analytical results are not provided. Finally, on the separation technique, you indicate that the test solution was filtred through a wool plug. However no justification or validation is provided for the separation method used.

32 Based on the above:

- The reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically you did not provide any information on the performance parameters of the analytical method (e.g. LOQ, LOD etc.), and no information on the results of the analytically determined exposure concentrations during the test. Therefore it not possible to conclude on the bioavailabilty of the

substance and whether the algae were exposed to the source substance during the test.

- Additional requirements applicable to difficult to test substances:

33 You have not demonstrated that saturation concentration was achieved due to the following:

i. As you have not provided an analytical method validation report, you have not demonstrated that the ICP-MS method is an appropriate analytical method to detect the dissolved fraction of the source substance. Therefore it is not possible to conclude if (apart of the boron ion) analytical method is appropriate to confirm the concentration of all the constituents (including the similar constituents of the Substance i.e. [redacted]).

ii. The results of the preliminary solubility study are not provided, therefore ECHA is not in a position to assess if the test solution preparation method is adequate to maximize the concentration of the test material in solution.

iii. Separation method, you have not justified nor demonstrated that the method applied in the aquatic toxicity test, including the use of wool filter as a separation method, allowed achieving maximum dissolved concentrations.

34 Therefore, the study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) in the corresponding OECD TG.

2.3. Conclusion 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 source 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.

On this basis, the information requirement is not fulfilled.

2.4. Study design and test specifications

OECD TG 201 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under request 1

3. Ready biodegradability

35 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

3.1. Information provided

You have provided an OECD TG 301B study.

3.2. Assessment of information provided

36 We have assessed this information and identified the following issues:

3.2.1. The provided study does not meet the information requirement

37 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

38 Technical specifications impacting the sensitivity/reliability of the test

a) The inoculum must not be pre-adapted to the test material;

39 Reporting of the methodology and results

a) The source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
b) The results of measurements at each sampling point in each replicate is reported in a tabular form;

Your registration dossier provides an OECD TG 301B study showing the following:

Technical specifications impacting the sensitivity/reliability of the test

a) The inoculum was pre-adapted to the test material;

40 Reporting of the methodology and results

a) The inoculum concentration in the test is not reported;
b) The results of measurements at each sampling point in each replicate are not reported in a tabular form

41 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically the inoculum is adapted. Therefore, the test does not qualify as a ready biodegradability test (ECHA guidance R.7b.9.).
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability, therefore it is not possible to conduct an independent assessnment and verify whether the validity criteria were met.

42 Therefore, the requirements are not met. On this basis, the information requirement is not fulfilled.

In your comments to the draft decision, you have provided additional information on the study, which you claim has been updated in IUCLID. You have also attached a copy of the Full Study Report. The report includes the information listed above as missing in the dossier and clarifies that the inoculum was not adapted.

The information provided as part of your comments addresses the incompliances identified above. However, as the information is still currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

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

The compliance check was initiated on 08 June 2021.

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

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

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 9 months from the date of adoption of the decision.

In your comments on the draft decision,you requested ECHA to extend the standard granted time to a total of 12 months. Your request was based on the fact that the Substance is difficult to test since it an UVCB and has a low water solubility, for these reasons, "*it will take time to develop and implement an appropriate analytical method to satisfy the requirements in the draft decision*".

ECHA agrees that based on the type of the Substance (an UVCB) and its properties (poorly water soluble), the development of an appropriate analytical method might require more time. ECHA took this information into account and granted 3 months extension to the original deadline.

On this basis, ECHA has extended the deadline to 12 months

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 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

1.2. 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 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].

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, 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

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

- 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 synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.