~~Confidential~~

Helsinki, 06 June 2023

Addressees
Registrants of TEPA_Jointsubmission as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08/09/2021

Registered substance subject to this decision ("the Substance")
Substance name: amines, polyethylenepoly-, tetraethylenepentamine fraction
EC number/List number: 292-587-7

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 information by ***14 December 2026***.

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

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

4. Simulation testing on ultimate degradation in surface water, also requested below (triggered by Annex VIII, Section 9.2.)

5. Identification of degradation products, also requested below (triggered by Annex VIII, Section 9.2.)

6. Bioaccumulation in aquatic species, also requested below (triggered by Annex VIII, Section 9.3., Column 2.)

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

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

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

9. 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.

10. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.25/OECD TG 309)

11. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13/OECD TG 305)

The reasons for the requests 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.

In the requests above, the same study has been requested under different Annexes or for different information requirements.
In the case of the same study requested under different Annexes, this is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided.
In all cases, only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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 requests
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 requests

Contents

~~Confidential~~

Reasons common to several requests

0.1. Test material not representative of the Substance

1 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). The Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents". Such information includes purity, composition, carbon chain length distribution, amination degree, branching, isomerisation, , depending on the type of UVCB substance.

2 In your dossier, you have conducted the studies for the following information requirements:

- Short-term toxicity test to aquatic invertebrates (Annex VII, Section 9.1.1)
- Growth inhibition study on aquatic plants and Algae (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

3 The studies have been conducted with a UVCB substance without further information than its identifier (i.e., EC No. 292-587-7). It does not include information on carbon chain length distribution, amination degree, branching and isomerisation.

4 In the absence of detailed information on the UVCB test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance for any of the information requirements listed above.

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

5 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

1.1. Information provided

6 You have provided a short-term toxicity study on daphnia magna (1989) with the Substance.

1.2. Assessment of the information provided

1.2.1. Test material not representative of the Substance

7 As explained under Section 0.1 of the general section common to several requests, in the absence of detailed information on the UVCB test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

1.2.2. The provided study does not meet the specifications of the test guideline

8 To fulfil the information requirement, a study must comply with OECD TG 202 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results

b) the test procedure is reported (e.g. composition of the test medium, water hardness, DOC content);

c) the methods used to prepare stock and test solutions is reported.

9 In the provided study:

Characterisation of exposure

a) no analytical monitoring of exposure was conducted

Reporting of the methodology and results

b) on the test design, you have not specified composition of the test medium, water hardness, DOC content;

c) the methods used to prepare stock and test solutions is not reported.

10 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical monitoring of

exposure concentrations, you have not demonstrated that test animals were adequately exposed to the test material over the exposure period;

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of adequate information on the test medium composition, it is not possible to assess whether the test was conducted under conditions that are consistent with the test guideline requirements.

11 On this basis, the specifications of OECD TG 202 are not met.

12 Therefore, the information requirement is not fulfilled.

13 In your comments on the draft decision, you agree with ECHA's assessment. You explain that you agree to perform further testing on aquatic toxicity that will also take into account the requirements of the OECD GD 23. You intend to use a tiered approach that "*will include possible adaptions of information requirements according to the general provisions of Annex XI, Section 1.5 of the REACH Regulation*".

14 ECHA acknowledges your intention to fulfil the standard information requirement, including by relying on a read-across approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance of your future adaptation(s) can currently be made. You remain responsible for complying with this decision by the set deadline.

1.3. Study design and test specifications

15 The Substance is difficult to test due to the adsorptive properties (Log K_{oc} > 3.5) and ionised at all environmental pHs. OECD TG 202 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 202. 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 solution.

16 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).

17 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

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

2.1. Information provided

19 You have provided a growth inhibition study on aquatic plants/algae (1990) with the Substance.

2.2. Assessment of the information provided

2.2.1. Test material not representative of the Substance

20 As explained under Section 0.1 of the general section common to several requests, in the absence of detailed information on the UVCB test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

2.2.2. The provided study does not meet the specifications of the test guideline

21 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

Reporting of the methodology and results

b) the test design is reported (*e.g.*, number of replicates);

c) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, biomass density at the beginning of the test);

d) the methods used to prepare stock and test solutions are reported;

e) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported. Algal biomass is normally determined based on dry weight per volume, or alternatively as cell counts or biovolume using microscopy or an electric particle counter. If an alternative method is used (e.g. flow cytometry, *in vitro* or *in vivo* fluorescence, or optical density), a satisfactory correlation with biomass must be demonstrated over the range of biomass occurring in the test;

f) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

22 In the provided study:

Characterisation of exposure

a) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

b) on the test design, you have not specified number of replicates;

c) on the test conditions, you have not specified the composition of the test medium, biomass density at the beginning of the test;

d) on the test procedure, you have not specified the methods used to prepare stock and test solutions;

e) the method used to determine algal biomass is not reported. You have not either reported evidence of correlation between the measured parameter and dry weight or cell numbers over the range of biomass occurring in the test;

f) tabulated data on the algal biomass determined daily for each treatment group and control are not reported, or on the coefficient of variation for the whole period and of the biomass increase in the control culture.

23 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical monitoring of exposure concentrations, you have not demonstrated that test organisms were adequately exposed to the test material over the exposure period;
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of the information listed under points b) to f) above, it is not possible to assess (i) whether the test was conducted under conditions that are consistent with the test guideline requirements, (ii) whether the validity criteria of the test guideline were met and (iii) the interpretation of the study results.

24 On this basis, the specifications of OECD TG 201 are not met.

25 Therefore, the information requirement is not fulfilled.

26 Your comments already described in Section 1.2. and ECHA's reply equally applies to this information requirement.

2.3. Study design and test specifications

27 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 and test specifications" under request 1.

Reasons related to the information under Annex VIII of REACH

3. Short-term toxicity testing on fish

28 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

3.1. Information provided

29 You have provided a short-term toxicity study on fish (1989) with the Substance.

3.2. Assessment of the information provided

3.2.1. Test material not representative of the Substance

30 As explained under Section 0.1 of the general section common to several requests, in the absence of detailed information on the UVCB test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

3.2.2. The provided study does not meet the specifications of the test guideline

31 To fulfil the information requirement, a study must comply with OECD TG 203 and the specification(s) of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Validity criteria

a) the analytical measurement of test concentrations is conducted;

Reporting of the methodology and results

b) the test procedure is reported (e.g., composition of the test medium, acclimation of fish prior to testing, feeding of the fish, removal of faeces);
c) the methods used to prepare stock and test solutions is reported;
d) for semi-static tests, dissolved oxygen, pH, salinity (if relevant) and temperature measured prior to and after each water renewal are reported. The results of hardness and TOC determinations in the dilution water are reported;
e) mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4.

32 In the provided study:

Validity criteria

a) no analytical measurement of test concentrations was conducted;

Reporting of the methodology and results

b) on the test procedure, you have not specified the composition of the test medium, how fish were acclimatised prior to testing, and whether fish were fed and faces removed during the test;
c) the methods used to prepare stock and test solutions is not reported;
d) the dissolved oxygen and pH measured are not reported nor of the water hardness and TOC results in the test prior and after test renewal;

e) tabulated data on mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) obtained on at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4 for each treatment group and control are not reported.

33 Based on the above,

- the validity criteria of OECD TG 203 are not met in the absence of any analytical monitoring, and
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of the information listed under points b) to e) above, it is not possible to assess (i) whether the test was conducted under conditions that are consistent with the test guideline requirements, and (ii) the interpretation of the study results.

34 On this basis, the specifications of OECD TG 203 are not met.

35 Therefore, the information requirement is not fulfilled.

36 Your comments already described in Section 1.2. and ECHA's reply equally applies to this information requirement.

3.3. Study design and test specifications

37 OECD TG 203 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 and test specifications" under request 1.

4. Simulation testing on ultimate degradation in surface water

38 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

4.1. Triggering of the information requirement

39 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable (i.e. <70 % degradation in an OECD 301D), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;

- it potentially meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

40 Your registration dossier provides the following:

- the Substance is not readily biodegradable (0% degradation after 28 days in OECD TG 301D);
- the Substance is an ionisable substance and therefore high potential for bioaccumulation cannot be excluded based on available information;

41 Furthermore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 6. of this decision), and
- it is not possible to conclude on the toxicity of the Substance see requests 1, to 3 and 7-8 of this decision).
- Under section 2.3 of your IUCLID dossier, you conclude that the Substance is potentially P/vP but not B/vB. In support of your conclusion you provide the following additional information:
  - On persistency you state that "The substance can be regarded as non biodegradable in the aquatic and terrestrial environment. The substance is considered to be potentially persistent based on the results of the screening tests".
  - On bioaccumulation you state that "The substance is considered cationic at environmental pH levels, a log Pow range of -3.42 to -2.60 was calculated for the substance".

42 However, as explained above, the bioaccumulation potential of the Substance may not be solely driven by lipophilicity and therefore, log Kow is not a reliable criterion to exclude that the Substance may be B/vB.

43 Therefore, the additional information from your PBT assessment is not adequate to conclude that the Substance is not a potential PBT/vPvB substance.

44 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the additional information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

45 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

46 In your comments on the draft decision, you acknowledge that the information from your dossier is not adequate to conclude on the PBT properties of the Substance and you agree to generate further information. You intend to use a tiered approach that "*will include possible adaptions of information requirements according to the general provisions of Annex XI, Section 1.5 of the REACH Regulation*". You explain that "*as a first step the registrant will assess the biological breakdown products that may be formed in the environment through the use of an appropriate QSAR model (e.g. the EAWAG-BBD Pathway Prediction System or CATALOGIC). This will be followed by an assessment of the available information on these substances, in order to investigate their potential PBT/vPvB properties. The assessment will include the use of appropriate QSAR models to estimate their biodegradation potential, bioaccumulation potential, as well as their toxicity. All generated data will be appropriately documented to support any QSAR calculations (i.e. QMRF and QPRF documentation)*".

47 ECHA acknowledges your intention to fulfil the standard information requirement, including by relying on a read-across approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance of your future adaptation(s) can currently be made. You remain responsible for complying with this decision by the set deadline.

4.2. Information requirement not fulfilled

48 The information provided, its assessment and the specifications of the study design are addressed under request 9.

5. Identification of degradation products

49 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

50 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

51 As already explained in request 4., the Substance is a potential PBT/vPvB substance.

52 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

53 Your comments already described in Section 4.1. and ECHA's reply equally applies to this information requirement.

5.1. Information requirement not fulfilled

54 The information provided, its assessment and the specifications of the study design are addressed under request 10.

6. Bioaccumulation in aquatic species

55 Under Annex VIII, Section 9.3., Column 2, further information on bioaccumulation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the bioaccumulation properties of the substance.

56 Therefore, this information requirement is triggered in case if for example additional information on bioaccumulation as set out in Annex XIII, point 3.2.2., is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1. of that Annex.

57 As already explained in request 4., the Substance is a potential PBT/vPvB substance.

58 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

59 Your comments already described in Section 4.1. and ECHA's reply equally applies to this information requirement.

6.1. Information requirement not fulfilled

60 The information provided, its assessment and the specifications of the study design are addressed under request 11.

Reasons related to the information under Annex IX of REACH

7. Long-term toxicity testing on aquatic invertebrates

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

7.1. Information provided

62 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substance:

(i) a long-term toxicity study on *Daphnia magna* (1991) with the source substance Amines, polyethylenepoly-, triethylenetetramine fraction, EC 292-588-2

7.2. Assessment of the information provided

7.2.1. Read-across adaptation rejected

63 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.

64 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).

65 You provide a read-across justification document in IUCLID Section 13.

66 You predict the properties of the Substance from information obtained from the following source substance(s):

- Amines, polyethylenepoly-, triethylenetetramine fraction, EC no. 292-588-2

67 You provide the following reasoning for the prediction of (eco)toxicological properties: "*structural similarity and mode of action and similar fate and similar (eco)toxicological effects: The ecotoxicological and toxicological profiles of the target and source substances are expected to be comparable due to the similar physico-chemical properties of all substances and the similar outcomes*".

68 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

69 We have identified the following issues with the prediction of long-term toxicity on aquatic invertebrates:

7.2.1.1. Incomplete characterisation of the group members (UVCB)

70 Under Annex XI, Section 1.5., Structural similarity for UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) must be established on the basis of similarities in the structures of the constituents, together with

the concentration of these constituents and variability in the concentration of these constituents. Qualitative compositional as well as quantitative characterisation of the individual constituents of these substances must be provided, to the extent that this is measurable (Guidance on IRs and CSA, Section R.6.2.5.5.).

71 The Substance and the source substance are UVCBs composed of non-protonated ethylene amines including linear, branched and cyclic ethylene amines. However, you have provided no information on carbon chain length distribution, amination degree, branching and isomerisation of the individual constituents of the source substance.

72 Without qualitative and quantitative information on the compositions of the Substance and of the source substance, it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

7.2.1.2. Inadequate or unreliable study on the source substance

73 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 test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211, and meet the specifications of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) for semi-static tests, test animals are individually held;

Characterisation of exposure

b) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results

c) water quality monitoring within the test vessels (i.e. pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is reported;

d) the full record of the daily production of living offspring during the test by each parent animal is provided;

e) the number of deaths among the parent animals (if any) and the day on which they occurred is reported.

74 In study (i):

Technical specifications impacting the sensitivity/reliability of the test

a) the test was conducted under semi-static conditions. You report that 5 animals were present in each test vessel

Characterisation of exposure

b) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

c) water quality monitoring within the test vessels: pH, temperature and dissolved oxygen concentration, TOC and/or COD and hardness are not reported;

d) the full record of the daily production of living offspring during the test [by each parent animal is not provided;

e) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;

75 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, as the test animals were not held individually the coefficient of variation for control reproductive output cannot be assessed. Furthermore, in the absence of analytical monitoring of exposure concentrations, you have not demonstrated that test organisms were adequately exposed to the test material over the exposure period
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of the information listed under points c) to e) above, it is not possible to assess (i) whether the test was conducted under conditions that are consistent with the test guideline requirements, (ii) whether the validity criteria of the test guideline were met and (iii) the interpretation of the study results.

76 On this basis, the specifications of OECD TG 211 are not met.

77 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 of the corresponding OECD TG.

78 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. On this basis, your read-across approach under Annex XI, Section 1.5. is rejected.

79 Therefore, the information requirement is not fulfilled.

80 Your comments already described in Section 1.2. and ECHA's reply equally applies to this information requirement.

7.3. Study design and test specifications

81 OECD TG 211 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 and test specifications" under request 1.

8. Long-term toxicity testing on fish

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

83 You have adapted this information requirement and provided the following justification: "*Based on the low acute toxicity to fish determined in the available short-term toxicity test and the low bioaccumulation potential a long-term toxicity of the substance is not anticipated. The available results on acute toxicity indicate that fish are less sensitive than invertebrates or algae. A long-term study with aquatic invertebrates is available (read across). Hence due to animal welfare reasons and to avoid unnecessary vertebrate tests, long-term toxicity testing with fish is not proposed*".

8.1. Assessment of the information provided

8.1.1. Your justification to omit the study has no legal basis

84 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

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

86 Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

87 Therefore, the information requirement is not fulfilled.

88 Your comments already described in Section 1.2. and ECHA's reply equally applies to this information requirement.

8.2. Study design and test specifications

89 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

90 OECD TG 210 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 and test specifications" under request 1.

9. Simulation testing on ultimate degradation in surface water

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

9.1. Information provided

92 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.2. To support the adaptation, you have provided following justification: "*In accordance with Annex IX column 2 simulation testing in water does not need to be conducted as CSA does not indicate the need for further investigations*".

93 In addition, you have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing). To support the adaptation, you have provided the following justification: "*simulation tests in water and sediment are deemed not necessary. The environmental exposure assessment for the substance indicates no risk for the aquatic and sediment compartment (all RCR< 1; please refer to Chapter 9 and 10 of the Chemical Safety Report for detailed information)*".

9.2. Assessment of the information provided

9.2.1. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

94 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed or may be required by ECHA if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this

provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2., Column 1.

95 Therefore, your adaption is rejected.

9.2.2. Substance-tailored exposure-driven testing adaptation rejected

96 Under Annex XI, Section 3.2(a)(ii) and (iii), a relevant and appropriate predicted no effect concentration (PNEC) must be derived and the results of the exposure assessment must show that exposures are always well below the PNEC, i.e. risk characterisation ratios RCRs must always be well below 1.

97 For substances satisfying the PBT and vPvB criteria of Annex XIII long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As a result, for such substances, PNECs and PECs cannot be derived with sufficient reliability to demonstrate that the ratio between PECs and the PNEC are always well below 1.

98 As explained in request 4., the information from your dossier does not allow excluding that the Substance is PBT/vPvB.

99 Therefore, you have neither demonstrated that an appropriate PNEC can be derived nor that RCRs are well below 1. On this basis, your adaptation is rejected.

100 Therefore, the information requirement is not fulfilled.

9.3. Study design and test specifications

101 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section 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.

102 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) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

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

104 As specified in Guidance on IRs and CSA, Section 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 material 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) (Guidance on IRs and CSA, Section 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.

105 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; Guidance on IRs and CSA, Section R.11.4.1.).

106 In your comments to the draft decision, you explain that the "*OECD TG 309 mainly provides guidance for single-component substances and therefore the testing of multi-component/UVCB substances presents methodological difficulties. These difficulties include the separation of single components as well as problems related to the recommended low starting concentrations in the OECD 309 test guideline*".

107 ECHA acknowledges your comments and notes that Appendix 4, Section 2.2 of this draft decision already describes approaches to conduct environmental testing for substances containing multiple constituents.

10. Identification of degradation products

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

10.1. Information provided

109 You have not submitted any information for this requirement.

110 Therefore, the information requirement is not fulfilled.

10.2. Study design and test specifications

111 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section 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.

112 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

113 You must obtain this information from the degradation study requested in request 9.

114 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 9.) 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).

11. Bioaccumulation in aquatic species

115 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

11.1. Information provided

116 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.3.2.. To support the adaptation, you have provided following justification: "*the study does not need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3*".

11.2. Assessment of the information provided

11.2.1. The log K_{ow} is not a valid descriptor of the bioaccumulation potential of the Substance

117 Under Section 9.3.2., Column 2, first indent of Annex IX to REACH, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

118 A low log K_{ow} (i.e. log K_{ow} < 3) on its own may be used to show low potential for bioaccumulation only if the potential for bioaccumulation of the substance is solely driven by lipophilicity. This excludes, for example, situations where the substance is surface active or ionisable at environmental pH (pH 4 – 9).

119 Your registration dossier provides an adaptation stating that the log K_{ow} is < 3 without further explanation.

120 The Substance is ionisable as it is dissociated at all environmental pHs.

121 Therefore, log K_{ow} is not a valid descriptor of the bioaccumulation potential of the Substance and your adaptation is rejected.

122 Therefore, the information requirement is not fulfilled.

11.3. Study design and test specifications

123 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

124 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

125 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are 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 14 March 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

In your comments on the draft decision, you explain that "*Due to the period of Christmas and end of year period, the Consortium is not able to gather comments from all the member registrants, we kindly request ECHA to extend the deadline for one month, by 16 February 2023"*. As already explained to you in an informal communication sent on 23 January 2023, the timeline for providing comments on draft decisions under Article 41 to REACH (compliance check) is set to 30 days under Article 50 to REACH. The commenting period has already exceptionally been extended by 15 days to account for the Christmas period. ECHA therefore has not granted an extension.

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 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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].
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

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

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

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include 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

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

have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.
- The reported composition must also include other parameters relevant for the property to be tested, in this case carbon chain length distribution, amination degree, branching and isomerisation of constituents.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

2.2. 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
- 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.