~~Confidential~~

Helsinki, 13 November 2023

Addressee
Registrant of JS_EC_846-447-2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
07/01/2020

Registered substance subject to this decision ("the Substance")
Substance name: reaction products of benzaldehyde diethylenetriamine and triethylenetetramine, hydrogenated
EC number/List number: 846-447-2

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 ***22 February 2027***.

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

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

1. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106)

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

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

4. 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

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

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

7. 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.

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

9. 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 addressee of the decision and its 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.

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 request(s)
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 request(s)

Contents

Reasons related to the information under Annex VIII of REACH

1. Adsorption/ desorption screening

1 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

1.1. Information provided

2 You have provided the following information:

(i) an OECD 121 (2018) with the Substance;

(ii) an adaptation under Column 2 of Annex VIII, Section 9.3.1. To support the adaptation, you have provided following justification: "*the substance has a low octanol water partition coefficient and the adsorption potential of this substance is related to this parameter*";

(iii) you have also provided the following justification for omitting this information requirement: "*CSA shows that exposure of aquatic environment is highly unlikely. Material is used as part of the reactive system of epoxy resin and curing agent. Release of material from this system is not possible once it is fully reacted and it is fully reacted*".

1.2. Assessment of the information provided

1.2.1. The provided study (i) does not meet the specifications of the test guideline

3 To fulfil the information requirement, a study must comply with the OECD TG 121 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Key parameter to be measured

a) Coverage of the key parameter which is the adsorption coefficient K_{oc} as determined by the partition of the test material between the mobile solvent phase and the cyanopropyl stationary phase using reverse phase HPLC.

4 In study (i):

Key parameter to be measured

a) The adsorption coefficient K_{oc}, as determined by the partition of the test material between the mobile solvent phase and the cyanopropyl stationary phase using reverse phase HPLC, was not determined.

5 Based on the above, the key parameter of OECD TG 121 is not covered by study (i).

6 Therefore, the specifications of OECD 121 are not met.

1.2.2. The adaptation (ii) under Column 2 of Annex VIII, Section 9.3.1 is rejected

7 Under Annex VIII, Section 9.3.1, Column 2, first indent, the study may be omitted if the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient). In order to adapt this information requirement based on low octanol-water partition coefficient (log K_{ow}), lipophilicity must be the sole

characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

8 You claim that the Substance has a low octanol-water partition coefficient and has therefore low potential for adsorption.

9 In section 5 of your dossier, you state that "the test item indicated that it would be positively ionized (protonated amines) across the environmentally relevant pH range" and this also supported by the information presented in section 1.2 of your dossier regarding the compositional information of the substance.

10 The information in your dossier indicates that the Substance is ionisable and therefore, other mechanisms than lipophilicity may drive absorption.

11 However, you have not demonstrated that lipophilicity is the sole characteristic driving adsorption potential and that log K_{ow} is not a valid descriptor for assessing the adsorption potential of the Substance.

12 Therefore your adaptation is rejected.

1.2.3. Your justification (iii) to omit the study has no legal basis

13 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex VIII, Section 9.3.1, Column 2.

14 Your justification to omit this information under point (iii) does not refer to any legal ground for adaptation under Annex XI to REACH or Annex VIII, Section 9.3.1., Column 2.

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

16 Therefore, the information requirement is not fulfilled.

2. Simulation testing on ultimate degradation in surface water

17 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.

2.1. Triggering of the information requirement

18 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. <60 degradation in an OECD 301D).
- 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 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.

19 Your registration dossier provides the following:

- the Substance is not readily biodegradable (8% degradation after 28 days in OECD TG 301D);
- as explained in request 2, the Substance is ionisable substance and therefore high potential for bioaccumulation cannot be excluded based on available information.

20 Furthermore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 10 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Requests 1, 6 and 7 of this decision).

21 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

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

2.2. Information requirement not fulfilled

23 The information provided, its assessment and the specifications of the study design are addressed under request 7.

3. Identification of degradation products

24 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.

25 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.

26 As already explained in request 2, the Substance is a potential PBT/vPvB substance.

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

28 The information provided, its assessment and the specifications of the study design are addressed under request 8.

4. Bioaccumulation in aquatic species

29 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.

30 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.

31 As already explained in request 2, the Substance is a potential PBT/vPvB substance.

32 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

4.1. Information requirement not fulfilled

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

Reasons related to the information under Annex IX of REACH

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

35 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification "CSA shows that exposure of aquatic environment is highly unlikely. The substance is used as part of the reactive system of epoxy resin and curing agent. Release of the substance from this system is not possible once it is fully reacted".

5.2. Assessment of the information provided

5.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

36 Annex IX, Section 9.1., Column 2 does not provided any basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

37 Your adaptation is therefore rejected.

38 On this basis, the information requirement is not fulfilled

39 In the comments to the draft decision, you explain that you intend to address this information requirement by using data from a structurally similar substance. You state that "*a detailed read across justification will be provided together with the results of the study*".

40 ECHA takes note of your indention to adapt this information requirement on the basis of Annex XI, Section 1.5, of the REACH Regulation. As the information in your comments is not sufficient for ECHA to make any assessment, no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

6. Long-term toxicity testing on fish

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

6.1. Information provided

42 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification: "CSA shows that exposure of aquatic environment is highly unlikely. Material is used as part of the reactive system of epoxy resin and curing agent. Release of material from this system is not possible once it is fully".

6.2. Assessment of the information provided

6.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

43 Annex IX, Section 9.1., Column 2 does not provide any basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

44 Your adaptation is therefore rejected.

45 On this basis, the information requirement is not fulfilled

46 In the comments to the draft decision, you explain that you intend to address this information requirement by using data from a structurally similar substance. You state that "*a detailed read across justification will be provided together with the results of the study*".

47 ECHA takes note of your indention to adapt this information requirement on the basis of Annex XI, Section 1.5, of the REACH Regulation. As the information in your comments is not sufficient for ECHA to make any assessment, no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

6.3. Study design and test specifications

48 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.).

7. Simulation testing on ultimate degradation in surface water

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

7.1. Information provided

50 You have provided the following justification for omitting this information requirement: "CSA shows that exposure of aquatic environment is highly unlikely. Material is used as part of the reactive system of epoxy resin and curing agent. Release of material from this system is not possible once it is fully reacted short time after use".

7.2. Assessment of the information provided

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

51 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.2, Column 2.

52 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.2., Column 2.

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

54 Therefore, the information requirement is not fulfilled.

55 In your comments to the draft decision, you do not agree to perform the requested study. You state that "*the substance is regarded not biodegradable in ready tests and better degradation is also not expected in simulation studies*". You note that "*in accordance with ECHA Guidance R11. Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment*". Therefore, you consider that the data

gap can be fulfilled by conducting an inherent biodegradation test according to OECD TG 302.

56 ECHA takes note of your indention to perform an inherent biodegradation test according to OECD TG 302. However, while the information from an OECD TG 302 test may provide relevant information in the context of the PBT/vPvB assessment, such information cannot be regarded as equivalent to a simulation study on ultimate degradation in surface water. In case you decide to omit the requested study, you will need to submit an adaptation meeting the requirements of either the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.1.2, Column 2. In any case, you remain responsible for complying with this decision by the set deadline.

7.3. Study design and test specifications

57 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.

58 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.).

59 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.

60 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. Paragraph 52 of the OECD TG 309 provides that the "*total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances*". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

61 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, 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 (NER - summary 2019 (europa.eu)).

62 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.).

8. Identification of degradation products

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

8.1. Information provided

64 Your registration dossier does not include any information on degradation products identity.

65 Therefore, the information requirement is not fulfilled.

66 In the comments to the draft decision, you do not agree to perform the requested study and refer to your comments already addressed under Request 7.

67 As already explained under Request 7, in case you decide to omit the requested information, you will need to submit an adaptation meeting the requirements of either the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 9.2.3., Column 2. In any case, you remain responsible for complying with this decision by the set deadline.

8.2. Study design and test specifications

68 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.

69 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.

70 You must obtain this information from the degradation studies requested in request 8.

71 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 8) 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).

9. Bioaccumulation in aquatic species

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

9.1. Information provided

73 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 on bioaccumulation does not need to be conducted as the substance has a low potential for

bioaccumulation (log Kow <= 2.2) and direct or indirect exposure to the environment is unlikely to occur".

9.2. Assessment of the information provided

9.2.1. The provided adaptation does not meet the criteria of Annex IX, Section 9.3.2., Column 2

74 Under Annex IX, Section 9.3.2., Column 2 provides that the study may be omitted:

(i) if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes. 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 present in ionised form(s) at environmentally relevant conditions (pH 4 – 9)

(ii) if direct and indirect exposure of the aquatic compartment is unlikely. Therefore, it must be demonstrated that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

75 Relevant to the indent (i) of Section 9.3.2., Column 2, your registration dossier provides an adaptation stating that the log K_{ow} is < 3 without further explanation. Furthermore, the Substance is ionisable. In the section 5 of your registration dossier you report that "An assessment of the test item indicated that it would be positively ionized (protonated amines) across the environmentally relevant pH range".

76 In your comments to the draft decision, you explain that the "*log Kow of all eleven components of the substance is well under 3*" as predicted by Wskowwin v1.42 (EpiSuite) and that, for those constituents, the "*highest estimated BCF is 13.44 L/kg ww*" using BCFBAF v3.01 (EpiSuite). You also argue that: (1) "*ionization lowers the tendency of a chemical to bioaccumulate, compared to non-ionized chemicals*" and (2) "*there is no known bioaccumulation mechanism other than passive diffusion driven by hydrophobicity for the* [Substance]". However, as acknowledged by you, the Substance is outside of the applicability domain of the selected QSAR models as they only apply to non-ionic substances. Furthermore, you do not substantiate your claim that no other bioaccumulation mechanisms than passive diffusion to lipid would be relevant for the Substance. Finally, you bring various arguments and QSAR predictions without integrating the various pieces of information and explaining on the basis of a scientific rationale why they would allow for an adequate and reliable conclusion. Therefore, your comments on the draft decision do not change ECHA's assessment.

77 Relevant to the indent (ii) of Section 9.3.2., Column 2, in your chemical safety assessment, you report the following uses: Formulation into mixture (ERC2), Use at industrial site [redacted] and Widespread use leading to inclusion into/onto article (outdoor) (ERC8f). In the section 10 of your CSA you report significant total releases to the environment per year from all life cycle stages of the substance in the aquatic environment (5.18 x 10^3 kg/year).

78 In your comments on the draft decision, you acknowledge that "*that results from CSA indicate that there is a substantial amount entering the environment*".

79 Therefore, log K_{ow} is not a valid descriptor of the bioaccumulation potential of the Substance and the uses provided in the dossier indicates releases to the environment and contradict your statement of unlikely direct and indirect exposure.

80 Therefore your adaptation is rejected and the information requirement is not fulfilled.

9.3. Study design and test specifications

81 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.

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

83 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 June 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.

ECHA took into account your comments and has removed the request for Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.).

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.

Following the Board of Appeal's decision in case A-001-2022 ECHA revised the study design specifications for meeting the information requirement for simulation testing on ultimate degradation in surface water (Annex VIII, column 2, section 9.2 and/or Annex IX, first column, section 9.2.1.2).

Appendix 3: Addressee 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]

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

(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 have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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

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 (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.