~~Confidential~~

Helsinki, 23 November 2022

Addressees
Registrant(s) of JS_219-207-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
21/10/2016

Registered substance subject to this decision ("the Substance")
Substance name: 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate
EC/List number: 219-207-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***2 June 2025***.

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

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

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

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

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)

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in

accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report**, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

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

Failure to comply

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

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

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

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Assessment of test material

1 The test material in a study must be representative for the Substance (Article 10 and Recital 19 of REACH; ECHA Guidance R.4.1).

2 For the endpoints listed below, you have identified the test material as "Cycloaliphatic Epoxy Resin ERL-4221", without further information, including composition.

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

3 In the absence of composition information on the 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.

4 In your comments to the draft decision, you specify that "*the test material charactisation is available in a separate report (*[redacted]*)* […]. *The average purity of the diepoxide monomer was* [redacted]*% and the sample remained stable over the course of the toxicity studies*". You propose to "*update the registration dossier to be more transparent on the substance identity tested*".

5 ECHA acknowledges your expression of intent to update your registration dossier. Regarding the additional information submitted in your comments, ECHA points out that the relative amount of diepoxide monomer falls within the substance identity profile (SIP) of the Substance (i.e., >=80<=100 % (w/w)). However, your comments do not include any information on the nature and quantity of impurities which, according to the information you provided, amount for [redacted]% of the test material used to generate information on the above information requirements. In the absence of this information you still fail to demonstrate that the test material is representative for the Substance, and ECHA cannot verify whether the test material is representative for the Substance.

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

7 You have provided a study on short-term toxicity to aquatic invertebrates (2000) with Cycloaliphatic Epoxy Resin ERL-4221.

1.2. Assessment of the information provided

1.2.1. Unclear test material

8 As explained in Section 0.1., the test material used for the study is not clear, and ECHA therefore cannot verify the reliability of the provided information.

1.2.2. The provided study does not meet the information requirement

9 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

10 Technical specifications impacting the sensitivity/reliability of the test

a) the test medium fulfils the following condition(s): hardness between 140 and 250 mg/L (as $CaCO_3$);

11 Reporting of the methodology and results

b) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported;
c) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

12 Your registration dossier provides an OECD TG 202 study showing the following:

13 Technical specifications impacting the sensitivity/reliability of the test

a) the test was conducted with a test medium having the following characteristics: hardness of 609 mg/L (as $CaCO_3$)

14 Reporting of the methodology and results

b) the dissolved oxygen and pH measured at least at the beginning and end of the test is not reported;
c) on the analytical method adequate information, i.e. performance parameters of the method including specificity, recovery efficiency, precision and limits of determination (detection limit and limit of quantification) are not reported.

15 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the reported hardness of the test medium is more than two times higher than the maximum allowed water hardness in the test guideline. It is not known how the higher hardness of water influences on e.g. bioavailability

of the test material or behaviour of the test animals in the test.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, the dissolved oxygen and pH were measured during the test but it is not clear if the measurements were made at the beginning and end of the test. As a result of this, it is not possible assess if the oxygen concentration and pH remained at acceptable levels throughout the study. Also, the performance parameters of the analytical method were not reported and it is not possible to assess if the reported test material concentrations are reliable and represent the true test material concentrations in the test medium with sufficient accuracy.

16 In your comments to the draft decision, you clarified that hardness of the test medium was wrongly reported in your dossier and that it was within the acceptable range (see point a) above). Further, you provided the missing information listed under points b) and c) in the above. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

17 Furthermore, on the basis of the considerations set out in point 1.2.1, the information requirement is not fulfilled.

18 In your comments to the draft decision, you specify that "*a new longterm toxicity data on aquatic invertebrates will be conducted on the registered substance* […], [you] *consider*[] *that an adaptation according to Section 9.1.1., Column 2, second indent of Annex VII of REACH will be also appropriate to fulfil the standard information requirement*".

19 As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

2. Growth inhibition study aquatic plants

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

2.1. Information provided

21 You have provided a study on toxicity to freshwater algae (2000) with Cycloaliphatic Epoxy Resin ERL-4221.

2.2. Assessment of the information provided

2.2.1. Unclear test material

22 As explained in Section 0.1., the test material used for the study is not clear, and ECHA therefore cannot verify the reliability of the provided information.

2.2.2. The provided study does not meet the information requirement

23 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

24 Characterisation of exposure

a) the test media prepared specifically for analysis of exposure concentrations during

the test is treated identically to those used for testing (*i.e.* inoculated with algae and incubated under identical conditions);

25 Reporting of the methodology and results

b) the test conditions are reported (*e.g.*, composition of the test medium);
c) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
d) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;
e) adequate information on the analytical method (including performance parameters of the method) is provided;

26 Your registration dossier provides an OECD TG 201 study showing the following:

27 Characterisation of exposure

a) the test media prepared specifically for analysis of exposure concentrations was not inoculated with algae;

28 Reporting of the methodology and results

b) on the test conditions, you have not specified composition of the test medium;
c) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
d) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported;
e) on the analytical method adequate information, i.e. performance parameters of the method including specificity, recovery efficiency, precision and limits of determination (detection limit and limit of quantification) are not reported.

29 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the test media prepared specifically for analysis of exposure concentrations was not inoculated with algae. As the presence of algae may modify the test material concentration in the test medium, the applied approach does not necessarily reflect the true concentration in the test medium where the algae growth measurements were made. Therefore, it is not possible to conclude on the reliability of the measured concentrations during the test.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of tabulated biomass data, it is not possible to conduct an independent assessment of whether the validity criteria of the test guideline were met. Also, healthy appearance of the algae was not reported and it is not possible to conclude that the inoculum culture provided healthy algae for the test. In addition, performance parameters of the analytical method were not reported and it is not possible to assess validity of the analytical method to assess test material concentration in the test medium when the performance parameters are not reported.

30 In your comments to the draft decision, you provided the missing information listed under point b) to e) above. However, as the information is currently not available in your registration dossier, the deficiency remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

31 In your comments, you also agree that "*the test material concentration in the actual algae exposure vessel was not documented in the study report (point a) above)*". As a result, you agree to repeat the study.

32 Based on the information from your dossier and from your comments to the draft the issues specified under points 2.2.1 and 2.2.2 remain. Therefore, the information requirement is not fulfilled.

3. Ready biodegradability

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

3.1. Information provided

34 You have provided a ready biodegradability screening study according to the OECD TG 301B (1999) with Cycloaliphatic Epoxy Resin ERL-4221.

3.2. Assessment of information provided

3.2.1. Unclear test material

35 As explained in Section 0.1., the test material used for the study is not clear, and ECHA therefore cannot verify the reliability of the provided information.

3.2.2. The provided study does not meet the information requirement

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

37 Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
b) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is reported.

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

39 Reporting of the methodology and results

a) the source and the concentration of the suspended solids of the inoculum are reported, however, its concentration as bacterial cells/mL in the test is not reported. Also, it is not clear if and how pre-conditioning treatment was applied, since it is only stated that inoculum was "*adapted*";
b) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is not reported;

40 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically,

- the bacterial cell density is not reported and the applied cell density cannot be confirmed to be within the required range from 10^7 to 10^8 cells per mL. Furthermore, it is not clear if the applied inoculum was adapted before the use in the test and therefore, it is not possible to confirm that non-adapted inoculum was used in the test.
- the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test are not reported and the reliability of the calculated results cannot be confirmed.

41 Therefore, the requirements of OECD 301B are not met.

42 In your comments, you "*agree with ECHA assessment*". Yet you "*consider that the study is valid and reliable with all necessary information in the study report*". You state that you "*will update the registration dossier based on this additional information and* [you] *consider*[] *that it's not necessary to repeat this study*". On the deficiencies listed above, you provide the following justifications:

(i) On point a) above, you state that "*bacteria cell density in the inoculum is not required in the OECD test guideline, only suspended solids concentration is required. The report included suspended solids concentration which is 30 mg/L*".

ECHA notes that Table 2 from the OECD TG 301 is entitled "*test conditions*" and therefore should be seen as the conditions under which the various test methods described in the test guideline must be conducted. The limit values for the inoculum density in mg/L (e.g., for sludge or soil) or mL/L (e.g., for surface water or effluent) are set to ensure that the introduction of exogeneous organic matter in the test system is within an acceptable range. Such parameter does not provide a direct estimate of bacterial biomass (as the density of bacteria in, for e.g., a sludge sample or a secondary effluent may vary by orders of magnitude). Accordingly, Appendix R.7.9-1 of ECHA Guidance on IRs and CSA specifies inoculum conditions as cell density (cells/mL) present in a relevant media (e.g. surface waters, unchlorinated sewage treatment works, activated sludge). In the absence of supporting information to demonstrate that the inoculum concentration used in the provided study allowed reaching an adequate bacterial density, you have not demonstrated that the inoculum density was consistent with the specifications of the corresponding test method.

(ii) On point a) above, you also claim that "*non-adapted activated sludge was used for the study*".

ECHA understands that you intend to clarify that the inoculum was not adapted to the test material contrary to what is currently stated in your dossier. However, ECHA notes that you failed to provide a description of pre-conditioning treatment for the inoculum as requested in the draft decision. Therefore, the deficiency remains.

(iii) On point b) above, you state that "*the IC and TC in the test material suspension in the mineral medium at the beginning of the test is not needed*".

However, ECHA notes that one of the validity criteria of the OECD TG 301B states that the inorganic carbon content (IC) of the test material suspension in the mineral medium at the beginning of the test is < 5% of the total carbon (TC). This is because high inorganic carbon content in the the test material suspension in the mineral medium at the beginning of the test may bias adequate estimation of the mineralisation of the test material. In the absence of this information, you failed to demonstrate that this validity criteria from the OECD TG 301 B was met.

43 Based on the information from your dossier and from your comments to the draft decision the issues specified under points 3.2.1 and 3.2.2 remain. Therefore, the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

4. Short-term toxicity testing on fish

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

4.1. Information provided

45 You have provided a short-term toxicity study on fish (2000) with Cycloaliphatic Epoxy Resin ERL-4221.

4.2. Assessment of the information provided

4.2.1. Unclear test material

46 As explained in Section 0.1., the test material used for the study is not clear, and ECHA therefore cannot verify the reliability of the provided information.

4.2.2. The provided study does not meet the information requirement

47 To fulfil the information requirement, a study must comply with OECD TG 203 (Article 13(3) of REACH). Therefore, the following specifications must be met:

48 Reporting of the methodology and results

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

49 Your registration dossier provides an OECD TG 203 study showing the following:

50 Reporting of the methodology and results

a) on the analytical method, adequate information, i.e. performance parameters of the method, including specificity, recovery efficiency, precision and limits of determination (detection limit and limit of quantification), are not reported;
b) 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.

51 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically,

- the performance parameters of the analytical method was not provided and the reliability of the measured concentrations of the test material cannot be assessed. This has also influence on the reliability of the reported effective concentrations.
- tabulated data on mortalities and especially on sub-lethal effects were not provided and it is not possible to assess the pattern of the sub-lethal effects and how they emerged during the test.

52 Therefore, the requirements of OECD TG 203 are not met.

53 In your comments on the draft decision, you provided adequate information on the analytical method used to conduct this study (see point a) above). You also provided some additional information on mortalities and sub-lethal effects. However, only semi-quantitative information is reported on mortalities (i.e. <10% or > 30%) and no quantitative information is provided on sub-lethal effects. Therefore, the reporting of the study remains insufficient to fully assess its reliability.

54 Based on the information from your dossier and from your comments to the draft decision the issues specified under points 4.2.1 and 4.2.2 remain. Therefore, the information requirement is not fulfilled.

55 In you comments to the draft decision, you further state that "*a new long-term toxicity data on fish will be conducted on the registered substance* […], [you] *consider*[] *that an adaptation according to Section 9.1.3., Column 2, second indent of Annex VIII of REACH will be also appropriate to fulfil the standard information requirement*".

56 As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

Reasons related to the information under Annex IX of REACH

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

58 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: *"In accordance with the guideline requirements Cycloaliphatic Epoxide Resin ERL-4221 cannot be classified as readily biodegradable. However, the test substance is expected to fully degrade as shown by the results of the biodegradation test in water provided (GLP and guideline compliant). Measured Log Pow values for Cycloaliphatic Epoxide Resin ERL-4221 are less than 3.0. The potential for Cycloaliphatic Epoxide Resin ERL-4221 to bioaccumulate in the tissues of organisms that inhabit aquatic or terrestrial matrices contaminated with Cycloaliphatic Epoxide Resin ERL-4221 is therefore negligible. Therefore it is considered that this study is not required."*

5.2. Assessment of the information provided

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

59 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to invertebrates under Column 1 (see by analogy the Decision of the Board of Appeal in case A-011-2018).

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

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

62 On this basis, the information requirement is not fulfilled.

63 In your comments to the draft decision, you agree with the deficiency identified above.

64 You further state in your comments that "[w]*hile the substance does not meet the standard waiver options as listed in Annex XI criteria point 2 "Testing is technically not possible" and point 3 "Substance-tailored exposure-driven testing",* [you] *want*[] *to emphasize that Annex XI criteria point 1.3 "Qualitative or Quantitative-structure- activity relationship ((Q)SAR)" and point 1.5 "Grouping of substances and read-across approach are possible adaptation to omit this standard information*". Therefore you intend to "*further investigate the two latest possible adaptation (QSAR and read-across approach) before deciding if a new experimental study is needed*". You state that "[a] *Long-term toxicity testing on aquatic invertebrates (EU C.20./OECD TG 211) will be conducted on the registered substance as a last resort".*

65 As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. Please note that this decision does not consider updates of the registration dossiers after. You remain responsible for complying with this decision by the set deadline.

6. Long-term toxicity testing on fish

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

6.1. Information provided

67 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information: *"In accordance with the guideline requirements Cycloaliphatic Epoxide Resin ERL-4221 cannot be classified as readily biodegradable. However, the test substance is expected to fully degrade as shown by the results of the biodegradation test in water provided (GLP and guideline compliant). Measured Log Pow values for Cycloaliphatic Epoxide Resin ERL-4221 are less than 3.0. The potential for Cycloaliphatic Epoxide Resin ERL-4221 to bioaccumulate in the tissues of organisms that inhabit aquatic or terrestrial matrices contaminated with Cycloaliphatic Epoxide Resin ERL-4221 is therefore negligible. Therefore it is considered that this study is not required."*

6.2. Assessment of the information provided

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

68 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

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

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

71 On this basis, the information requirement is not fulfilled.

72 In your comments to the draft decision, you agree with the deficiency identified above.

73 You further state in your comments that "*[w]hile the substance does not meet the standard waiver options as listed in Annex XI criteria point 2 "Testing is technically not possible" and point 3 "Substance-tailored exposure-driven testing", [you] want[] to emphasize that Annex XI criteria point 1.3 "Qualitative or Quantitative-structure- activity relationship ((Q)SAR)" and point 1.5 "Grouping of substances and read-across approach" are possible adaptation to omit this standard information*". Therefore you intend to "*further investigate the two latest possible adaptation (QSAR and read-across approach) before deciding if a new experimental study is needed. This strategy is aligned to the New Approach Methodologies (NAMs) and to the 3Rs – reduction, refinement, or replacement of animal use – principle, as REACH specifically requires information to be generated whenever possible by means other than vertebrates animal tests*". You state that "[a] *Long-term toxicity testing on fish (EU C.47./OECD TG 210) will be conducted on the registered substance as a last resort."*

74 As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore 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

75 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.).

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

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

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

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

The compliance check was initiated on 03 November 2021.

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

ECHA took into account your comments and did not amend the requests.

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 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]

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 all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance 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[3].

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