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Helsinki, 03 May 2023

Addressees
Registrants of JS_EHGE_219-553-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
19/03/2013

Registered substance subject to this decision ("the Substance")
Substance name: [[(2-ethylhexyl)oxy]methyl]oxirane
EC number: 219-553-6

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 ***10 August 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020);

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

3. Growth inhibition study 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

4. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487);

5. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490);

6. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.);

7. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats;

8. 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

9. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;

10. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit);

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

12. 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.

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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

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.);
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.);
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.);
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.);
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.;)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.);
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.);
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.).

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

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used.

4 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.

5 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.

6 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).

0.1.1. Predictions for toxicological properties

7 You predict the toxicological properties of the Substance from information obtained from the source substance: Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8) except for the short-term repeated dose toxicity (28-day) and the sub-chronic toxicity (90-day) for which you use the analogue substance Oxirane, mono[(C12-13-alkyloxy)methyl] derivs as source substance.

8 In the robust studies summaries of the respective source studies you provide the following reasoning for the prediction of subchronic toxicity study (90-day) and pre-natal developmental toxicological properties of the Substance:

9 Sub-chronic toxicity: “Study was performed according to test guideline and in compliant with GLP for Oxirane, mono[(C12-13-alkyloxy)methyl] derivs / ERC Nr 17, which is structurally similar to EHGE (EC#:219-553 -6).”

10 Pre-natal developmental toxicity: "Study was according to test guideline and in compliance with GLP for Oxirane, mono[(C12-14-alkyloxy)methyl] derivs / ERC Nr 17, which is structurally similar to EHGE (EC#:219-553 -6)".

11 You did not provide a reasoning for the prediction of the properties related to the other toxicological information requirements listed above.

12 ECHA understands that for the short-term repeated dose toxicity (28 day), the sub-chronic toxicity (90-day) and the pre-natal developmental toxicity information requirements, 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(s).

13 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.1.1.1. Absence of read-across documentation for the information requirements for genetic toxicity and sceening test for reproductive developmental toxicity

14 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

15 You have provided robust study summaries for the following studies conducted with other substances than the Substance in order to comply with the REACH information requirements:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

16 However, you have not provided documentation, as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substances.

17 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substances.

0.1.1.2. Inadequate read-across hypothesis for the information requirements for repeated-dose toxicity and pre-natal developmental toxicity

18 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis. This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the toxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

19 As explained in section 0.1.1., you have applied a read-across hypothesis only based on the structural similarity between the source substances and the Substanceto adapt the following standard information requirements:

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

20 However, your hypothesis does not explain why the structural differences between the substances do not influence the toxicological properties or do so in a regular pattern.

21 While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar toxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for the short-term repeated dose toxicity (28 day) properties, the sub-chronic toxicity (90-day) properties and the pre-natal developmental toxicity properties, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substances.

22 In the absence of such information, you have not established that the Substance and the source substances are likely to have similar properties.

23 Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.3. Inadequate or unreliable source studies

24 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

25 Specific reasons why the studies on the source substances do not meet these criteria are explained further below under the applicable information requirement sections 6, 9 and 10.

26 Therefore, no reliable predictions can be made for these information requirements.

0.1.1.4. Conclusion on the read-across approaches for toxicological properties

27 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substances. Your read-across approaches under Annex XI, Section 1.5. are rejected.

0.1.2. Predictions for ecotoxicological properties

28 You predict the properties of the Substance from information obtained from the following source substance:

29 Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., EC No. 271-846-8.

30 In the robust studies summaries of the respective source studies you provide the following reasoning for the prediction of aquatic toxicity properties (i.e. short-term toxicity on aquatic invertebrates, growth inhibition study aquatic plants and short-term toxicity on fish) of the Substance: ”Study was performed according to test guideline and in compliant with GLP for Alkyl (C12-C14) glycidyl ether, which is structurally similar to 2-Ethylhexyl glycidyl ether (EC#:219-553-6). Thus the study is used for read-across to avoid duplicate tests.” and “2-Ethylhexyl glycidyl ether (EC#: 219-553-6) is expected to have the similar property”.

31 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.

32 We have identified the following issue(s) with the prediction(s) of aquatic toxicity:

0.1.2.1. Inadequate read-across hypothesis

33 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis.

34 This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). It should explain why the differences in the chemical structures should not influence the ecotoxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

35 Your read-across hypothesis is only based on the structural similarity between the source substance and the Substance, which you consider a sufficient basis for predicting the properties of the Substance.

36 However, your hypothesis does not explain why the structural differences between the substances do not influence the ecotoxicological properties or do so in a regular pattern.

37 While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for the ecotoxicological properties short-term toxicity on aquatic invertebrates, growth inhibition study aquatic plants and short-term toxicity on fish, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substance.

0.1.2.2. Missing supporting information to compare the properties of the substances

38 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

39 Supporting information must include bridging studies to compare properties of the source substances.

40 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance.

41 For the source substance, you provide the studies used in the prediction in the registration dossier, which are not adequate as explained in section 0.1.2.3. below. Apart from those

studies, your registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

42 In the absence of such information, you have not established that the Substance and the source substances are likely to have similar properties.

43 Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2.3. Inadequate source studies for risk assessment / classification and labelling

44 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

45 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement sections, i.e. Requests 1, 3 and 8.

46 Therefore, no reliable predictions can be made for these information requirements.

0.1.2.4. Conclusion on the read-across approach for ecotoxicological properties

47 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

48 An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

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

(i) bacterial reverse mutation assay with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8) (1997);

1.2. Assessment of the information provided

50 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

51 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

52 To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

53 In the comments to the draft decision, you agree to perform the requested study.

2. Short-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

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

(i) a short-term toxicity study on aquatic invertebrates (2010) with the source substance Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., EC 271-846-8.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

56 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

57 In addition, ECHA identified endpoint specific issue(s) addressed below.

2.2.1.1. Inadequate source study for risk assessment / classification and labelling

58 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

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

60 For the Substance, you report a water solubility of 0.143 g/L (OECD TG 105) in your dossier and on this basis you conclude that the Substance is moderately soluble.

61 For the source substance, you do not report a water solubility value in your dossier.

62 There is evidence in the reported study (i) that the source substance is poorly water soluble, i.e. below 1 mg/L. Specifically, for the source substance nominal test concentrations ranging from 1 to 100 mg/L were prepared and analysed at the beginning of the test and after 48 h exposure. You report measured concentrations ranging from 0.0512 to 0.248 mg/L at the beginning of the test, indicating that the water solubility of the source substance is below 1 mg/L.

63 Therefore, the source substance is poorly water soluble and the provided short-term study (study i.) does not give a true measure of toxicity for the source substance.

64 Based on the above, the results of this study are not adequate for the purpose of classification and labelling and/or risk assessment.

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

66 In the comments to the draft decision, you agree that the study with the source substance is not suitable to fulfil the information requirement of the Substance.

67 Instead of performing a new OECD TG 202 study as requested, you propose to perform the long-term toxicity study on aquatic invertebrates (OECD TG 211) which is also requested by this decision (request 11).

68 You consider that the range finding study from OECD TG 211 would meet the information requirement of Short-term toxicity testing on aquatic invertebrates.

69 ECHA agrees that information on short-term toxicity to aquatic invertebrates could be generated by a range-finding study for long-term toxicity endpoint.

70 Furthermore, REACH Annex VII section 9.1.1 column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on invertebrates is available.

71 At present no long-term toxicity study on aquatic invertebrates (nor a range finding study) is provided in the IUCLID dossier, therefore no conclusion on the compliance can currently be made.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

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

(i) an algal growth inhibition study (2006) with the source substance Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., EC 271-846-8.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

74 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

75 In addition, ECHA identified endpoint specific issue(s) addressed below.

3.2.2. Inadequate source study for risk assessment / classification and labelling

76 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

77 For aquatic toxicity tests where the concentrations do not remain within 80-120% of nominal or initial measured concentrations, the effect values must be expressed relative to the geometric mean of the measured concentrations at the start and end of the test to reflect the actual exposure of the test organisms to the test substance (Guidance on IRs and CSA, Section R.7.8.1).

78 For study (i) with the source substance, you report a 72h NOEC value of 500 mg/L based on nominal concentration.

79 You indicate that in study (i) analytical monitoring of exposure concentrations was conducted, but you do not report the measured concentrations in your dossier. In the short-term toxicity to aquatic invertebrates study (OECD TG 202) with the source substance, the nominal concentrations ranged from 1 to 100 mg/L and the analytically measured concentrations ranged from 0.0512 to 0.248 mg/L at the start of the test, and after 48h they were below the limit of quantification of the analytical method.

80 Therefore, even in the absence of information on measured concentrations in study (i), there is evidence from the analytically measured concentrations in the OECD TG 202 study that the concentrations of the source substance do not remain within 80-120% of nominal or initially measured. As a consequence, the reported effect value based on nominal concentration for study (i) does not reflect the actual exposure of the test organisms to the source substance.

81 Based on the above, the results of this study are not adequate for the purpose of classification and labelling and/or risk assessment.

82 On this basis, the information requirement is not fulfilled.In the comments to the draft decision, you agree to perform the requested study.

Reasons related to the information under Annex VIII of REACH

4. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

83 An *in vitro* cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

4.1. Information provided

84 You have adapted this information requirement by using Annex VIII, Section 8.4.2., column 2. To support the adaptation, you have provided the following information:

(i) Mammalian Erythrocyte Micronucleus Test (1997) with the source substance Oxirane, mono[(C12-14-alkyloxy)methyl] derivs.(EC 271-846-8)

4.2. Assessment of the information provided

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

86 Under Annex VIII, Section 8.4.2., column 2, the study usually does not need to be conducted "if adequate data from an *in vivo* cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the *in vivo* somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to the OECD TG 474 or 475, respectively.

87 The study (i) is described as a micronucleus assay, conducted with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8).

4.2.1. Read-across adaptation rejected

88 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

4.2.2. Column 2 criterion to omit the study is not met

89 Based on the reasons explained in section 4.2.1., the study (i) which you have submitted with a view to omit this information requirement based on Section 8.4.2., column 2 of Annex VIII to REACH is not considered as a reliable *in vivo* micronucleus test.

90 Therefore, your adaptation according to Section 8.4.2., column 2 is rejected and the information requirement is not fulfilled.

4.3. Specification of the study design

91 To fulfil the information requirement for the Substance, either *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

92 In the comments to the draft decision, you agree to perform the requested study.

5. In vitro gene mutation study in mammalian cells

93 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the in *vitro gene* mutation test in bacteria and the *in vitro* cytogenicity test.

5.1. Triggering of the information requirement

94 Your dossier contains an adaptation for an *in vitro* gene mutation study in bacteria, and an adaptation for an *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study.

95 The information for the *in vitro* gene mutation study in bacteria and for the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study provided in the dossier are rejected for the reasons provided in requests 1 and 4.

96 The result of the requests for an *in vitro* gene mutation study in bacteria and for an *in vitro* cytogenicity study in mammalian cells will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

97 Consequently, you are required to provide information for this information requirement, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

5.2. Information provided

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

(i) *In Vitro* Mammalian Cell Gene Mutation Test with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8) (1998);

5.3. Assessment of the information provided

99 We have assessed this information and identified the following issue(s).

100 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

101 In your comments on the draft decision you indicate that you do not consider it necessary to perform an *in vitro* gene mutation study in mammalian cells. You indicate your intentions to revise and consolidate your adaptation of the information requirements for an *in vitro* gene mutation study in mammalian cells according to Annex XI, Section 1.5.

102 You outline that the glycidylether function common to the Substance and the source substance is "*the chemical moiety that dominates toxicological and ecotoxicological properties (…) especially when compared to the inactive alkyl moieties*" of the Substance and the source substance.

103 You also refer to similarities in physico-chemical properties and in other toxicological and ecotoxicological properties to support your hypothesis that the Substance and the source substance are likely to have similar properties for the information requirements under consideration.

104 You explain that in case negative results are obtained in both the *in vitro* gene mutation study in bacteria (request 1 in this decision) and the *in vitro* cytogenicty study in mammalian cells (request 4 in this decision), these studies will provide suport for an enhanced read-across adaptation using information from an *in vitro* gene mutation study in mammalian cells available on the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8).

105 ECHA acknowledges your intentions to improve the toxicological profile of the Substance and your plans to refine your read-across approaches.

106 As indicated in your comments, this strategy relies essentially on data on the Substance which is yet to be generated and potentially on new data on the source substance which is not currently available in your dossier or in your comments. Therefore no conclusion on the compliance can currently be made.

5.4. Specification of the study design

107 To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

6. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days)

108 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

6.1. Information provided

109 You have adapted this information requirement by using Annex VIII, Section 8.6.1., Column 2. To support the adaptation, you have provided the following information:

(i) Statement in the Chemical Safety Report: *"a short-term toxicity study does not need to be conducted because a reliable sub-chronic (90 days) or chronic toxicity study is available, conducted with an appropriate species, dosage, solvent and route of administration [study scientifically not necessary / other information available]"*

(ii) Subchronic Dermal Toxicity: 90-Day Study (1997) with the source substance Oxirane, mono[(C12-13-alkyloxy)methyl] derivs.

6.2. Assessment of the information provided

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

111 Under Annex VIII, Section 8.6.1, Column 2, Paragraph 1, Indent 1, the study may be omitted if a reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant, provided that appropriate species, dosage, solvent and route of administration are used.

112 The study (ii) is described as a dermal sub-chronic toxicity conducted with the source substance Oxirane, mono[(C12-13-alkyloxy)methyl] derivs.

6.2.1. Read-across adaptation rejected

113 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

114 Furthermore, for the reasons explained in request 9 the study (ii) is not adequate for the purpose of classification and labelling and/or risk assessment and does not have an

adequate and reliable coverage of the key parameters addressed in the corresponding OECD TG.

6.2.2. Column 2 criterion to omit the study is not met

115 Based on the reasons explained in section 6.2.1., the study ii. which you have submitted with a view to omit this information requirement based on Section 8.6.1., Column 2 of Annex VIII to REACH is not considered as a reliable sub-chronic toxicity study (90-day).

116 Therefore, your adaptation according to Section 8.6.1., Column 2 is rejected and the information requirement is not fulfilled.

6.3. Specification of the study design

117 Annex VIII, Section 8.6.1., Column 2 provides that an experimental study for this information requirement is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

118 The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see request 9). According to Annex VIII, Section 8.6.1., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study (28 days) does not therefore need to be conducted.

119 Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

120 In your comments on the draft decision you indicate that you agree to perform the requested sub-chronic toxicity study (90 days) and to use this information to adapt the information requirement for a short-term repeated dose toxicity study (28 days) according to Annex VIII, Section 8.6.1., Column 2.

7. Screening for reproductive/developmental toxicity

121 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

7.1. Information provided

122 You have adapted this information requirement by using Annex VIII, Section 8.7.1., column 2. To support the adaptation, you have provided following information:

(i) Statement "*According to annex VIII, prenatal reproductive toxicity is available, so the screening for reproducition/developmental toxicity study does not need to be conducted"*.
(ii) Preliminary Developmental Toxicity Screen with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8).

7.2. Assessment of the information provided

123 Under Annex VIII, Section 8.7., column 2, the study does not need to be conducted if a pre-natal developmental toxicity study (OECD TG 414) is already available.

124 The study (ii) is described as a Preliminary Developmental Toxicity Screen conducted with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8).

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

7.2.1. Read-across adaptation rejected

126 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

127 Furthermore, for the reasons explained in request 10 the study (ii) is not adequate for the purpose of classification and labelling and/or risk assessment and does not provide an adequate and reliable coverage of the key parameters specified in the corresponding OECD TG.

7.2.2. Column 2 criterion to omit the study is not met

128 Based on the reasons explained in section 7.2.1., the study ii. which you have submitted with a view to omit this information requirement based on Section 8.7.1., Column 2 of Annex VIII to REACH is not considered as a reliable pre-natal developmental toxicity study.

129 Therefore, your adaptation according to Section 8.7.1., Column 2 is rejected and the information requirement is not fulfilled.

7.3. Specification of the study design

130 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

131 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

132 In your comments on the draft decision you indicate that you agree to perform the requested pre-natal developmental toxicity study requested in this decision and to use this information to adapt the information requirement for a screening for reproductive/developmental toxicity study according to Section 8.7.1., Column 2.

133 ECHA acknowledges your intentions to adapt the information requirement for a screening for reproductive/developmental toxicity study according to Section 8.7.1., Column 2.

134 However, since the information from the pre-natal developmental toxicity study is not yet available and reported in your dossier, the data gap persists.

8. Short-term toxicity testing on fish

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

8.1. Information provided

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

(i) a short-term toxicity to fish study (2006) with the source substance Oxirane, mono[(C12-14-alkyloxy)methyl] derivs., EC 271-846-8;
(ii) a short-term toxicity to fish study (1977) with the source substance Oxirane,

mono[(C12-14-alkyloxy)methyl] derivs., EC 271-846-8.

8.2. Assessment of the information provided

8.2.1. Read-across adaptation rejected

137 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

138 In addition, ECHA identified endpoint specific issue(s) addressed below.

8.2.1.1. Inadequate source studies for risk assessment / classification and labelling

139 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

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

141 For the Substance, you report a water solubility of 0.143 g/L (OECD TG 105) in your dossier and on this basis you conclude that the Substance is moderately soluble.

142 For the source substance, you do not report a water solubility value in your dossier.

143 As explained in Request 2, there is evidence in the reported short-term toxicity study on aquatic invertebrates that the source substance is poorly water soluble, i.e. below 1 mg/L. Specifically, for the source substance nominal test concentrations ranging from 1 to 100 mg/L were prepared and analysed at the beginning of the test and after 48 h exposure. You report measured concentrations ranging from 0.0512 to 0.248 mg/L at the beginning of the test, indicating that the water solubility of the source substance is below 1 mg/L.

144 Therefore, the source substance is poorly water soluble and the provided short-term studies (studies (i) and (ii)) do not give a true measure of toxicity for the source substance.

145 Based on the above, the results of this study are not adequate for the purpose of classification and labelling and/or risk assessment.

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

147 In the comments to the draft decision, you agree that the study with the source substance is not suitable to fulfil the information requirement of the Substance.

148 Instead of performing a new OECD TG 203 study as requested, you propose to perform the long-term toxicity study on fish (OECD TG 210) which is also requested in this decision (request 12).

149 You consider that the range finding study from OECD TG 210 would meet the information requirement of Short-term toxicity testing on fish.

150 We agree that information on short-term toxicity to fish could be generated by a range-finding study for long-term toxicity endpoint.

151 Furthermore, REACH Annex VII section 9.1.3 column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on fish is available.

152 At present, no long-term toxicity study on fish is provided in the IUCLID dossier, therefore no conclusion on the compliance can currently be made.

Reasons related to the information under Annex IX of REACH

9. Sub-chronic toxicity study (90-day)

153 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

9.1. Information provided

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

(i) Subchronic Dermal Toxicity: 90-Day Study with the source substance Oxirane, mono[(C12-13-alkyloxy)methyl] derivs (1997).

9.2. Assessment of the information provided

155 We have assessed this information and identified the following issue(s).

156 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

157 In addition, ECHA identified endpoint specific issue addressed below.

158 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment and 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.

159 As specified by Annex IX, 8.6.2 column 1, the sub-chronic toxicity study (90-day) should be performed using the "most appropriate route of administration, having regard to the likely route of human exposure."

160 As ECHA Guidance on IRs and CSA R 7.a (R.7.5.4.3.2) stipulates, "Concerning repeated dose toxicity testing, the oral route is the default one because it is assumed to maximise systemic availability (internal dose) of most substances.

161 However, on a case-by-case basis, the appropriateness of other routes of administration should also be assessed. Depending on the physico-chemical properties of a substance and the most relevant route of human exposure, the dermal or the inhalation route can also be appropriate as specified in Annexes VIII and IX to the REACH Regulation."

162 For the information requirement of sub-chronic toxicity study (90-day), Annex IX, 8.6.2 column 2 sets the conditions whereby testing by the dermal route or the inhalation route is more appropriate than testing by the default route of administration, i.e. oral.

163 More specifically, testing by the dermal route is appropriate if, among others, one of the following conditions is met:

- toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or
- systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or
- *in vitro* tests indicate significant dermal absorption, or
- significant dermal toxicity or dermal penetration is recognised for structurally-related substances.

164 Based on the information provided in your dossier, none of the conditions listed above are met.

165 Therefore, in this case the default route of administration applies and the test guideline for the corresponding study that shall normally be performed is the OECD TG 408.

166 The study (i) is described as a Subchronic Dermal Toxicity: 90-Day Study conducted with the source substance Oxirane, mono[(C12-13-alkyloxy)methyl] derivs.

9.2.1. Adequacy for the purpose of classification and labelling and/or risk assessment

167 As pointed out above, according to ECHA Guidance on IRs and CSA R 7.a (R.7.5.4.3.2) "Concerning repeated dose toxicity testing, the oral route is the default one because it is assumed to maximise systemic availability (internal dose) of most substances". You have not established that, for the source substance, testing via the dermal route would achieve comparable systemic availability (internal dose) to the oral route. Since the identification of systemic toxicity of a substance is dependent on the systemic availability achieved in a study, in the absence of this information, the results of study (i) do not reliably inform on the systemic toxicity of the source substance after repeated exposure as investigated in a study conducted according to the OECD TG 408.

168 Therefore, study (i) does not constitute a reliable basis to predict the properties of the Substance. Consequently the information from study (i) is not adequate for the purpose of classification and labelling and risk assessment for the Substance.

9.2.2. Adequacy and reliability of the coverage of the key parameters of the OECD TG 408

169 No information is provided on the nature of the investigations conducted as part of the study. In the absence of information on the nature of the investigations conducted as part of the study, you have not established that the study adequately and reliably covers the key parameters expected to be investigated in a study conducted according to the OECD TG 408.

170 Based on the above, the study is not adequate for the purpose of classification and labelling and/or risk assessment and does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 408.

171 Therefore, this study is not an adequate basis for your read-across predictions.

172 Your adaptation is rejected and the information requirement is not fulfilled.

9.3. Specification of the study design

173 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, and considering the guidance on IRs and CSA, Section R.7.5.6.3.2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

174 According to the OECD TG 408, the rat is the preferred species.

175 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

176 In the comments to the draft decision, you agree to perform the requested study.

10. Pre-natal developmental toxicity study in one species

177 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

10.1. Information provided

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

(i) Prenatal Developmental Toxicity Study via dermal route with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8) (1997).

10.2. Assessment of the information provided

179 We have assessed this information and identified the following issue(s).

180 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

181 In addition, ECHA identified endpoint specific issue addressed below.

182 Under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment and 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 414.

183 Therefore, the following specifications must be met:

a) at least 20 female animals with implantation sites for each test and control group are included;
b) the foetuses are examined for skeletal and soft tissue alterations (variations and malformations).

184 Furthermore, according to the ECHA Guidance R.7.6.2.3.2, "according to the test methods for reproductive toxicity which focus on the detection of reproductive hazards, the oral route (gavage, in diet, or in drinking water) is the "default" route, except for gases. (…) If another route of administration other than oral is used, the registrant should provide justification and reasoning for its selection".

185 The study (i) is described as a Prenatal Developmental Toxicity Study conducted via the dermal route with the source substance Oxirane, 2-((C12-14-alkyloxy)methyl)derivs (EC 271-846-8).

10.2.1. Adequacy for the purpose of classification and labelling and/or risk assessment

186 The study (i) has been conducted via the dermal route. You have not provided a justification that the source substance has a high dermal penetration and that testing via the dermal route would not underestimate the hazards of the source substance.

187 Furthermore, as indicated above, the ECHA Guidance R.7.6.2.3.2 requires that a justification and reasoning for the selection of another route of administration is provided when another route than the oral route is used. As you have not provided such a justification and reasoning for the selection of the dermal route, the information from the study (i) does not reliably inform on the pre-natal developmental toxicity of the source substance as investigated in a study conducted according to the OECD TG 414.

188 Therefore, study (i) does not constitute a reliable basis to predict the properties of the Substance.

10.2.2. Adequacy and reliability of the coverage of the key parameters of the OECD TG 414

189 According to the information provided in the dossier, the study (i) the following specifications are not according to the OECD TG 414:

a) 8 females were included in each test and control group;

b) data on the examination of the foetuses, including incidence and severity, are missing; in particular, the following investigations are missing: skeletal and soft tissue alterations (variations and malformations).

190 Therefore the study (i) does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 414.

191 Based on the above, the study (i) is not adequate for the purpose of classification and labelling and/or risk assessment and does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 414.

192 Therefore, this study is not an adequate basis for your read-across prediction.

193 Your adaptation is rejected and the information requirement is not fulfilled.

10.3. Specification of the study design

194 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

195 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

196 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

197 In the comments to the draft decision, you agree to perform the requested study.

11. Long-term toxicity testing on aquatic invertebrates

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

11.1. Information provided

199 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:

(i) *"The current available information is sufficient for C&L purpose, only if the CSA indicates the need to investigate further information of the aquatic toxicity of the substance in future. Thus it is not necessary to perform any new test"*.

11.2. Assessment of the information provided

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

200 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety

assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

201 Your adaptation is therefore rejected.

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

203 In the comments to the draft decision, you agree to perform the requested study.

12. Long-term toxicity testing on fish

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

12.1. Information provided

205 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:

(i) *"According to REACH Annex IX, this test is not proposed as there is no CSA result indicating it is necessary to investigate further effects on aquatic organisms"*.

12.2. Assessment of the information provided

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

206 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

207 Your adaptation is therefore rejected.

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

209 In the comments to the draft decision, you agree to perform the requested study.

12.3. Study design and test specifications

210 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).
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 01 February 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.

Deadline to submit the requested information in this decision

In the comments on the draft decision, you requested an extension of the deadline from 36 to at least 48 months from the date of adoption of the decision. You justified your request by referring to the need for sequential testing and due to anticipated limited laboratory capacity to conduct the studies.

The deadline set in the draft decision already accounts for sequential testing, where appropriate.

Furthermore, as indicated above, the deadline has already been extended beyond the standard deadline in order to accommodate potential limited laboratory capacity, and you did not provide any evidence (such as correspondence with laboratory/ies including the scheduling timelines for the studies in question of the testing facility/ies) to justify a further extension.

On this basis, ECHA has not modified the deadline.

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;

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]

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