~~Confidential~~

Helsinki, 04 June 2024

Addressee
Registrant of JS_68440062_FEUC as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
16 December 2015

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C18-unsatd., dimers, hydrogenated, 2-ethylhexyl esters
EC/List number: 500-214-9

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

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

2. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity requested below.

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

4. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; test method: EU C.47./OECD TG 210).

The reasons for the request(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 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)

Reasons common to several requests

0.1. Read-across adaptation rejected

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

- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Long-term toxicity testing on fish (Annex VIII, Section 9.1.3, column 2)

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. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

4 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).

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

0.1.1. Scope of the grouping of substances

0.1.1.1. Identification of source substances

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

- 2-ethylhexanol, EC 203-234-3 (source substance 1);
- Fatty acids, C18-unsatd., dimers, List 500-148-0 (source substance 2).

7 You provide the following reasoning for the prediction of toxicological properties: *"The target substance Fatty acids, C18-unsatd., dimers, hydrogenated, 2-ethylhexyl esters (CAS 68440-06-2) and the structurally similar source substance Fatty acids, C18-unsatd., dimers, 2-ethylhexyl esters (CAS 68334-05-4) both result from* [redacted]*."*

8 In addition, ECHA notes that you provided in your dossier a long-term fish toxicity study (ISO/DIS 10229-1, 1994) with the source substance Fatty acids, C18-unsatd., dimers, hydrogenated (List 500-231-1), which is not covered by your read-across justification document. You provide the following reasoning for the prediction of this information requirement: *"As no tests with Fatty acids, C18-unsatd., dimers, hydrogenated, 2-ethylhexyl esters (CAS No. 68440-06-2) are available, a read-across approach to the structurally similar Fatty acids, C18-unsatd., dimers, hydrogenated (CAS No. 68783-41-5) was conducted."*

9 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

0.1.2. Predictions for toxicological properties

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

10 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.).

11 Supporting information must include studies to compare properties of the target and source substances if the impact of exposure to the (parent) Substance on the prediction cannot be excluded (see section 0.1.2.2).

12 Your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) 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 with the Substance and the source substance(s).

13 For the source substances, you provide repeated dose toxicity as well as reproductive and developmental toxicity studies used in the prediction in the registration dossier. Apart from these studies, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that the target and source substances cause the same type of effects. In particular, you provided no study on the target substance relevant to the adapted information requirements for these endpoints (bridging study).

14 In the absence of such information, you have not established that the Substance and the source substances are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.2.2. Missing supporting information on the formation of hydrolysis products

15 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.).

16 As indicated above, your read-across hypothesis is based on the use of data from the primary metabolites of the target substance. In this context, information characterising the rate and extent of the (bio)transformation of the Substance is necessary to confirm the formation of the proposed hydrolysis products and to assess the impact of the exposure to the parent compound.

17 To demonstrate the absence of exposure to the parent compound, supporting information must include toxicokinetic information on the formation of the common compound(s).

18 However, you have not provided any experimental information about the (bio)transformation of the Substance to support your claims regarding the rate and extent of formation of the proposed hydrolysis products.

19 In the absence of this information, you have not provided supporting evidence establishing that the proposed hydrolysis products are formed as assumed in your read-across hypothesis, and allowing the assessment of the (lack of) impact of exposure to the parent compound. Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis.

0.1.2.3. Inadequate or unreliable source study

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

21 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement section 3. Therefore, no reliable predictions can be made for this information requirement.

0.1.3. Predictions for ecotoxicological properties

0.1.3.1. Absence of read-across documentation

22 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).

23 You have provided robust study summary for the study conducted with a substance other than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation to explain why this information is relevant for the Substance and why the properties of the Substance may be predicted from information on the source substance(s).

24 ECHA notes that while you do provide a read-across justification document in section 13 of the IUCLID dossier, this document does not mention the source substance Fatty acids, C18-unsaturated, dimers, hydrogenated, List number 500-231-1.

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

0.1.3.2. Inadequate or unreliable source study

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

27 Specific reasons why the study on the source substance does not meet these criteria are explained further below under the applicable information requirement in section 4. Therefore, no reliable predictions can be made for these information requirements.

0.1.4. Conclusion

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

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

29 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

30 In the provided OECD TG 105 (2014), the saturation concentration of the Substance in water was determined to be >9 – <23 µg/L.

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

1.2. Information provided

32 You have adapted this information requirement and provided the following justification:

- You claim that the available short-term aquatic toxicity studies indicate the lack of aquatic toxicity. Further, you claim that the available short-term test results show no sign that any test species is more sensitive than the others.
- You claim that the Substance has a high potential for adsorption and on this basis, it is expected to be removed by the sewage treatment plants.
- On this basis, you conclude that the chemical safety assessment does not indicate the need to investigate further the long-term toxicity to aquatic invertebrates.

1.3. Assessment of the information provided

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

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

34 You have provided an adaptation based on the outcome of the chemical safety assessment of the Substance, which you consider to be based on Annex VII, Column 2. However, your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

35 In any case, poorly water soluble substances require longer time to reach steady-state conditions and short term studies do not provide a true measure of the intrinsic aquatic toxicity of the Substance.

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

37 Therefore, the information requirement is not fulfilled.

1.4. Study design

38 The Substance is difficult to test due to the low water solubility (> 9 – < 23 µg/L) and adsorptive properties (Log K_{ow} > 10). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and

maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

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

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

- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

Reasons related to the information under Annex VIII of REACH

2. Short-term repeated dose toxicity (28 days)

41 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

2.1. Information provided

42 You have adapted this information requirement by using Annex VIII, Section 8.6.1, column 2 based on the following experimental data from the source substances according to Annex XI, Section 1.5. (Grouping of substances and read-across approach):

(i) a subchronic repeated-dose toxicity study (OECD TG 408, 1996) with the source substance 2-ethylhexanol, EC 203-234-3;
(ii) a subchronic repeated-dose toxicity study (OECD TG 408, 1996) with the source substance Fatty acids, C18-unsatd., dimers, List 500-148-0.

43 Given that your column 2 adaptation relies on a read-across approach, it will be assessed under the rules applicable for grouping of substances and read-across in accordance with Annex XI, Section 1.5.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

44 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.

45 Therefore, the information requirement is not fulfilled.

2.2.2. Study design

46 When there is no information available neither for the 28-day repeated dose toxicity (OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

47 The study design is addressed in request 3.

3. Screening for reproductive/developmental toxicity

48 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1.

3.1. Information provided

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

(i) a reproduction/developmental toxicity screening test (OECD TG 421, 2004) with the source substance Fatty acids, C18-unsatd., dimers, List 500-148-0.

50 You have also relied on an adaptation according to Annex VIII, Section 8.7.1, column 2. Given that your column 2 adaptation relies on a read-across approach, it will be assessed

under the rules applicable for grouping of substances and read-across in accordance with Annex XI, Section 1.5. That read-across approach is based on the following experimental data from the source substance:

(ii) a prenatal developmental toxicity study (OECD TG 414, 1991) with the source substance 2-ethylhexanol, EC 203-234-3.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

51 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.

52 In addition, specific reasons why the prenatal developmental toxicity study on the source substance 2-ethylhexanol (EC 203-234-3) does not meet the OECD TG 414 specifications are explained further below.

3.2.1.1. Inadequate or unreliable study on the source substance

53 As explained in the Appendix on Reasons common to several requests, the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that must normally be performed for a particular information requirement, in this case OECD TG 414. Therefore, the following specifications must be met:

a) the highest dose level aims to induce toxicity or aims to reach the limit dose.

54 However, in study (ii):

a) the highest dose levels tested was 191 mg/kg bw/d, which is below the limit dose of the test guideline, and no adverse effect were observed. Although you attempt to provide a rationale for this high dose setting by referring to effects observed in a developmental toxicity study with DEHP at equivalent dose levels of 2-ethylhexanol (1988), no such effects were observed in study (ii).

55 The information provided does not cover the specification(s) required by the OECD TG 414.

56 Therefore, study (ii) submitted in your adaptation does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

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

3.3. Study design

58 When there is no information available neither for the 28-day repeated dose toxicity study (OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

59 The information requirement for the 28-day repeated dose toxicity study is not fulfilled for the reasons explained under request 2.

60 Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats.

61 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1., Column 1).

62 Therefore, the study must be conducted in rats with oral administration of the Substance.

4. Long-term toxicity testing on fish

63 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

64 As already explained in request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information provided

65 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 from the source substances:

(iii) An ISO-10229 study (1994) with the source substance Fatty acids, C18-unsaturated, dimers, hydrogenated, List number 500-231-1.

66 In addition to the adaptation using Annex XI, Section 1.5. (Grouping of substances and read-across approach), you provide an adaptation using Column 2 of Annex VIII, Section 9.1.3. To support the adaptation, you have provided the following information:

- You claim that the available short-term aquatic toxicity studies indicate the lack of aquatic toxicity. Further, you claim that the available short-term test results show no sign that any test species is more sensitive than the others.
- You claim that the Substance has a high potential for adsorption and on this basis, it is expected to be removed by the sewage treatment plants.
- On this basis, you conclude that the chemical safety assessment does not indicate the need to investigate further the long-term toxicity to fish.
- You mention animal welfare.

4.3. Assessment of the information provided

67 We have assessed this information and identified the following issue:

4.3.1. Read-across adaptation rejected

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

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

69 As explained in the Appendix on Reasons common to several requests, the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 210. Therefore, the following specifications must be met:

Key parameter measured

a) no observed effect concentration (NOECs) and/or effect concentration (EC_{10}) are determined for parameters related to the survival and development of fish in early life stages from the stage of fertilized egg until the juvenile life-stage, including

- the stage of embryonic development at the start of the test, and
- hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
- the appearance and behaviour of larvae and juvenile fish.

70 In study (i):

Key parameter measured

a) the concentrations of the test material leading to no observed effect NOECs or EC10 were not estimated, in particular on the following parameter(s):

- the stage of embryonic development at the start of the test, and
- hatching of fertilized eggs and survival of embryos, larvae and juvenile fish, and
- the appearance and behaviour of larvae and juvenile fish.

71 You report that the the test was conducted on specimens that hatched 47 days before the study initiation (i.e. juveniles). Because of this, the study does not provide information on the stage of embryonic development at the start of the test, the hatching and survival of fertilized eggs, the appearance and behaviour of larvae.

72 Based on the above,

- the information provided does not cover the key parameter(s) required by the OECD TG 210.

73 On this basis, the specifications of OECD TG 210 are not met.

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

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

75 You have provided an adaptation based on the outcome of the chemical safety assessment of the Substance, which you consider to be based on Annex VIII, Column 2. However, your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

76 In any case, poorly water soluble substances require longer time to reach steady-state conditions and short term studies do not provide a true measure of the intrinsic aquatic toxicity of the Substance.

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

78 Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex VIII.

79 Your adaptation is therefore rejected.

80 Therefore, the information requirement is not fulfilled.

4.4. Study design

81 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.).

82 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.

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 (2023).
***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 12 April 2023.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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: Addressee(s) of this decision and their corresponding information requirements

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

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

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

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(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/group of constituents on the test results for the endpoint to be assessed. For example, if a constituent/group of constituents of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/group of constituents.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

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

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