~~Confidential~~

Helsinki, 23 May 2024

Addressee
Registrant of EO_JS_91031-57-1 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20 December 2022

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C16-18, isononyl esters
EC number: 292-960-4

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

DECISION ON TESTING PROPOSAL(S)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***30 November 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 also requested below (triggered by Annex VII, Section 9.1.1., Column 2).

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

2. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., Column 2).

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

3. Sub-chronic toxicity study (90 days), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD TG 408) in rats.

4. 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).

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

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

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

Information required depends on your tonnage band

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

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

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

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Contents

Reasons common to several requests

0.1. Read-across adaptation rejected

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

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.),
- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2; Annex IX, Section 9.1.5.).

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).

0.1.1. Predictions for toxicological properties

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

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

- Fatty acids, C16- 18, 2-ethylhexyl esters, EC 292-951-5.

7 You provide the following reasoning for the prediction of toxicological properties: "The source and the target substances are esters with the ester group being the common functional group of all substances. The substances are esters of aliphatic fatty alcohols and fatty acids… The considered substances (source and target substances) result from esterification of the alcohol with the respective fatty acid(s). Esterification is, in principle, a reversible reaction (hydrolysis). Thus, the alcohol and fatty acid moieties are simultaneously precursors and breakdown products of the read-across substances. Monoesters are hydrolysed by enzymes in the gastrointestinal tract. The rate varies depending on the acid and alcohol chain length, but is relatively slow compared with the ester bonds of triglycerides".

8 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.

0.1.1.1. Missing supporting information to compare properties of the substances(s)

9 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.).

10 As indicated above, 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 for the Substance and of the source substance(s).

11 For the source substance, you provide the study used in the prediction in the registration dossier. Apart from that study, 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 both substances cause the same type of effects.

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

0.1.2. Predictions for ecotoxicological properties

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

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

- 2-ethylhexyl octadec-9-enoate, EC 247-655-0.

15 You provide the following reasoning for the prediction of ecotoxicological properties:

16 "The target substance fatty acids, C16-18, isononyl esters (CAS 91031-57-1) is a multi-constituent substance consisting of C16 and C18 fatty acid esterified with the branched fatty alcohol isononanol (C9iso). The source substances are characterized by fatty acids and fatty alcohols of similar chain lengths. […] The mono-constituent source substance 1, 2-ethylhexyl oleate (CAS 26399-02-0), is an ester of the fatty acid oleic acid (C18) and the branched and chiral fatty alcohol 2-ethylhexanol (C8, branched). […] None of the selected source substances contains structural elements typical of a specific mode of action."

17 Further, you explain that the key points of similarities between the source substance and the target substance are "(i) Common precursor and break-down products of a mono-functional alcohol and a carboxylic (fatty) acid chain, which are esterified; (ii) Similar structural features are the ester bond between a mono-functional alcohol and a fatty acid chain; (iii) Similar physico-chemical properties are: physical state (liquid), low vapour pressure, high octanol/water partition coefficient and low water solubility. […] (iv) Common properties that result in similar environmental fate & ecotoxicological profiles: Considering the poor water solubility and the high potential for adsorption to organic soil and sediment particles, the main compartments for environmental distribution are expected to be soil and sediment. Nevertheless, the substances are not expected to persist in these compartments based on their ready biodegradability. […] (v) Similar metabolic pathways: Fatty acid alkyl esters are expected to be metabolised via enzymatic hydrolysis to the corresponding free fatty acids and the alcohols."

18 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.

0.1.2.1. Inadequate or unreliable study on the source substance(s)

19 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;

(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

20 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement section 5. Therefore, no reliable predictions can be made for these information requirements.

0.1.3. Conclusion

21 Based on the 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 to aquatic invertebrates

22 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

23 Under Section 4.8 of your technical dossier, you have provided an OECD TG 105 study (column elution).The saturation concentration of the Substance in water was below the limit of detection of the analytical method (i.e. < 13.3 µg/L).

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

25 The examination of the information provided as well as the selection of the requested test and the test design are addressed under request 5.

Reasons related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

26 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.

2.1. Triggering of the information requirement

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

28 The examination of the information provided, your considerations of alternative methods, of third party comments (if applicable), as well as the selection of the requested test and the test design are addressed under request 6.

Reasons related to the information under Annex IX of REACH

3. Sub-chronic toxicity study (90 days)

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

3.1. Information provided

30 You have submitted a testing proposal for a sub-chronic toxicity study (90 days) according to OECD TG 408 with the Substance.

31 Your registration dossier does not include any information for this information requirement.

32 ECHA requested your considerations for alternative methods to fulfil the information requirement for repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

33 ECHA agrees that a sub-chronic toxicity study (90 days) is necessary.

3.2. Study design

34 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

35 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity; Guidance on IRs and CSA, Section R.7.5.4.3.2.

3.3. Outcome

36 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

4. Pre-natal developmental toxicity study in a first species

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

4.1. Information provided

38 You have submitted a testing proposal for a PNDT study according to the OECD TG 414 with the Substance.

39 In the dossier you have also provided a pre-natal developmental toxicity study (1994) with the source substance Fatty acids, C16-18, 2-ethylhexylesters, EC 292-951-5, and a read-across justification document in IUCLID Section 13.

40 ECHA requested your considerations for alternative methods to fulfil the information requirement for repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

4.2. Assessment of the available information

41 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.

42 On the basis of the available information, ECHA agrees that generation of information to meet the information requirement 'PNDT study in a first species' is still necessary.

4.3. Third party comments

43 ECHA received third party information concerning the testing proposal during the third-party consultation.

44 A third party has commented "*The Registration Dossier for the substance (Fatty acids, C16-18, isononyl esters: EC 292-960-4) contains an acceptable (Reliability: Klimisch 2) pre-natal developmental toxicity study in the rat (OECD 414) with the read-across substance Fatty acids, C16-18, 2-ethylhexyl esters. Due to the availability of a read-across study, a further study with the registered substance is not required*."

45 The third party has proposed a testing strategy including a read across approach for you to consider.

46 ECHA notes that it is your responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5. Therefore, you may assess whether you can justify a read-across as suggested by the third party. If the information requirement can be met by way of adaptation, you may include the adaptation argument with all necessary documentation according to Annex XI, Section 1.5. in an updated registration.

4.4. Study design

47 You proposed testing in the rat as a first species.

48 You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

49 You proposed testing by the oral route.

50 ECHA agrees with your proposal.

4.5. Outcome

51 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

5. Long-term toxicity to aquatic invertebrates

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

5.1. Information provided

53 You have submitted a testing proposal for a Daphnia magna reproduction test according to OECD TG 211 with the Substance.

54 In the dossier you nevertheless also provide a study on chronic toxicity to aquatic invertebrates (1995) with the source substance 2-ethylhexyl octadec-9-enoate, EC 247-655-0, and a read-across justification document in IUCLID Section 13.

55 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on aquatic invertebrates. You provided the following considerations in the endpoint study record of the testing proposal: You indicate that you considered if the general adaptation possibilities of Annex XI of the REACH regulation are adequate to generate the necessary information. In particular, you include the following information that you consider relevant to grouping and read-across adaptation: "No long-term effects on aquatic invertebrates up to the limit of water solubility (NOEC (21 d) ≥ 1 mg/L (nominal), OECD 211, D. magna)".

5.2. Assessment of the information

56 On the basis of the information available from your registration dossier, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected for the reasons explained in Section 0.1. above. In addition, ECHA identified the following endpoint specific issue.

5.2.1. Inadequate or unreliable study on the source substance

57 As already explained in general terms in Section 0.1., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211 (Article 13(3) of REACH) . Therefore, the following specifications must be met:

Characterisation of exposure

a) if the concentration of the test material in semi-static tests is not expected to remain within ± 20 % of the nominal concentration, then all test concentrations must be determined when freshly prepared and at the time of renewal on one occasion during each week of the test;

b) where a measured concentration at the end of the exposure period indicates that the substance is not detected, the concentration may be taken as the limit of detection for the method (Guidance on IRs & CSA Chapter R.7b, Appendix R.7.8—1). In particular, where the water solubility is below the detection limit of the analytical method for a substance, and toxicity is recorded, the effect concentration for classification purposes may be considered to be less than the analytical detection limit (Guidance on the Application of the CLP Criteria, ANNEX I: AQUATIC TOXICITY, I.4.2 Poorly soluble substances).

58 In the study with source substance 2-ethylhexyl octadec-9-enoate, EC 247-655-0:

Characterisation of exposure

a) the test was conducted under semi-static conditions and the concentration of the test material was determined at 0h, 24h, 48h, and 72h. Further, you report a test duration of 21 days and the renewal of the test solution "*every 2 to 3 days*" ;

b) the test item could not be detected at the beginning of the exposure period, i.e. its concentration was below limit of detection (LOD) of 10 µg/L of the analytical method used (you report that "*Measured concentration of test substance were below 0.01 mg/L in the 1 mg/L as well as in the 100 mg/L* [i.e. in both of the two tested concentrations] *sample at all sampling times*"), but the effect concentrations were reported based on nominal concentrations.

59 Based on the above, the Substance is difficult to test due to being poorly water soluble and having a high potential for adsorption and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, it is unclear what

concentrations were the test organisms exposed to, as on the basis of your reporting the entire duration of the study was not covered in terms of sampling times, because the test concentrations during the second and third weeks of the test were not determined. Further, the analytical monitoring was unable to differentiate between the two tested concentrations and showed that the measured concentration were below the LOD in both treatment groups. Yet, you report different observed effects in the two treatment groups (you report that in the 100 mg/L nominal concentration treatment group, 90% of the parent animals died on day 19). Further, you report the resulting 21-day NOEC values for mortality and reproduction as ≥1 mg/L (i.e. based on a nominal test concentration). Because of this, the reliability of the NOEC value cannot be independently confirmed by ECHA.

60 On this basis, the specification(s) of OECD TG 211 are not met.

61 Therefore, the study submitted in your adaptation does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG (Article 13(3) of REACH).

62 ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

5.3. Study design

63 The proposed Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (Guidance on IRs and CSA, Section R.7.8.4.1.).

64 The Substance is difficult to test due to the low water solubility (<13.3 µg/L) and adsorptive properties (log K_{oc} >5). 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 solutions.

65 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).

66 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.

5.4. Outcome

67 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

6. Long-term toxicity testing on fish

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

6.1. Information provided

69 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test according to OECD TG 210 with the Substance.

70 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. In your testing proposal, you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

71 In addition, in the endpoint summary of the long-term toxicity to fish endpoint in your dossier, you refer to Annex VIII, Section 9.1.3., Column 2 and information from acute aquatic toxicity studies on similar substances to conclude, with additional reference to animal welfare, that a study would not be necessary.

6.2. Assessment of the information

72 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. There are no specific Column 2- rules for ommission of the standard information required under Annex IX, Section 9.1.6.

73 As far as you mention read-across in the context of discussing acute toxicity study information ECHA notes, for the purpose of completeness, that in your read-across justification document in IUCLID section 13 you set out yourself that there are no available long-term fish toxicity data that could be read-across.

74 On a final note, ECHA points out that minimisation of vertebrate animal testing is not on its own a legal ground for adaptation.

75 ECHA therefore agrees that an appropriate study on long-term toxicity on fish is needed.

6.3. Study design

76 The proposed Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (Guidance on IRs and CSA, Section R.7.8.4.1.).

77 OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under request 1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in ‘Study design’ under request 5.

6.4. Outcome

78 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.

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

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 26 May 2023.

ECHA held a third party consultation for the testing proposal(s) from 30 June 2023 until 14 August 2023. ECHA received information from third parties (see corresponding Appendix/Appendices).

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

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

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

ECHA did not receive any comments within the commenting period.

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, with the corresponding requests in this decision provided within parenthesis:

- 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

(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 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.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

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