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Helsinki, 08 August 2023

Addressee(s)
Registrant of JS_85566-16-1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
31 August 2022

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C13-15-branched and linear
EC/List number: 287-625-4

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 information under requests 1, 2, 4, and 5 below by ***13 November 2025*** and information under requests 3 and 6 below by ***13 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. Extended one-generation reproductive toxicity study also requested below (triggered by Annex IX, Section 8.7.3., column 1)

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

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

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

6. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) by oral route, in rats, **with analogue substance isotridecan-1-ol (EC No. 248-469-2)**, specified as follows:

- At least two weeks premating exposure duration for the parental (P0) generation;
- The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or

deaths in P0 animals as specified further in Appendix 1, or follow the limit dose concept (as specified in section 6.3.3.). The reporting of the study must provide the justification for the setting of the dose levels;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning; and
- Cohorts 2A and 2B (Developmental neurotoxicity).

You must report the study performed according to the above specifications. Any expansion of the study must be scientifically justified.

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(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes or for different information requirements.

In the case of the same study requested under different Annexes, this is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided.

In all cases, only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

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

Appendix 1: Reasons for the decision

Contents

Reasons for the decision(s) related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 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

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.

2 Under Section 4.8 of your technical dossier, you have provided an OECD TG 105 study (shake-flask). The saturation concentration of the Substance in water was determined to be 0.68 mg/L.

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

4 The examination of the information provided as well as the selection of the requested test and the test design are addressed under request 4.

Reasons for the decision(s) related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

5 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

6 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.

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

8 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 5.

Reasons for the decision(s) related to the information under Annex IX of REACH

3. Extended one-generation reproductive toxicity study

9 An extended one-generation reproductive toxicity study (EOGRTS; OECD TG 443) is an information requirement under Annex IX, Section 8.7.3. if the available repeated dose toxicity studies indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

10 Your dossier contains a repeated dose toxicity study OECD TG 408 with analogue substance 2-propylheptan-1-ol (EC No. 233-126-1) ([redacted] 1996). 2-propylheptan-1-ol belongs to the same chemical category of 'Oxo Alcohols C9 to C13' as the proposed source substance isotridecan-1-ol (EC No. 248-469-2) (OECD SIDS, 2006), and is therefore considered to provide relevant repeated-dose information for the proposed source substance. For evaluation of your read-across approach, see section 6.2. below.

11 The OECD TG 408 study conducted with 2-propylheptan-1-ol (EC No. 233-126-1) indicates concerns in relation with reproductive toxicity. More specifically, the OECD TG 408 study shows histopathological changes in the thyroid gland (diffuse follicular cell hypertrophy, grade 2, observed in 7/10 male rats of the 600 mg/kg bw/day test group).

12 Therefore, the concern for reproductive toxicity must be further investigated.

13 ECHA agrees that an EOGRTS is necessary to address the identified concerns in relation with reproductive toxicity.

14 For the assessment of the testing proposal, see Request 6.

4. Long-term toxicity testing on aquatic invertebrates

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

4.1. Information provided to fulfil the information requirement

16 You have submitted a testing proposal for a Daphnia magna reproduction test (test method: EU C.20/OECD TG 211).

17 Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

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

4.2. Test selection and study specifications

19 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.).

20 The Substance is difficult to test due to the low water solubility (0.68 mg/L) and adsorptive properties (logkow > 5.6). 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.

21 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 components).

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

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- 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.

4.3. Outcome

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

24 In your comments you agree to conduct the study.

5. Long-term toxicity testing on fish

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

5.1. Information provided to fulfil the information requirement

26 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210).

27 Your registration dossier does not include any information on long-term toxicity on fish.

28 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. 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.

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

5.2. Test selection and study specifications

30 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.).

31 OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under request 4, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Test selection and study specifications' under request 4.

5.3. Outcome

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

33 In your comments you agree to conduct the study.

Reasons for the decision(s) related to the information under Annex X of REACH

6. Extended one-generation reproductive toxicity study

34 The basic test design of an extended one-generation reproductive toxicity study (EOGRTS) is a standard information requirement under Annex X. Furthermore, Annex X, Section 8.7.3., Column 2 defines when the study design needs to be expanded.

6.1. Information provided to fulfil the information requirement

35 You have submitted a testing proposal for an EOGRTS according to OECD TG 443, to be conducted with analogue substance isotridecanol (EC No. 248-469-2).

36 ECHA requested your considerations for alternative methods to fulfil the information requirement for Toxicity to reproduction. You provided your considerations, and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

37 ECHA agrees that an EOGRTS is necessary.

6.2. Evaluation of read-across approach

38 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.

39 You have provided a read-across justification document in IUCLID Section 13.2.

40 In IUCLID section 7.8.1, you propose to conduct an EOGRT study with analogue substance isotridecanol (EC No. 248-469-2). ECHA therefore understands that you propose that the properties of the Substance, in terms of reproductive toxicity, may be predicted from data that is to be generated with source substance (1) Isotridecanol (EC No. 248-469-2). Furthermore, according to the read-across justification document, you consider that source substance (2) Propylheptanol (EC No. 233-126-1) provides relevant information on repeated-dose toxicity properties of the Substance.

41 The Substance and source substances (1) and (2) show structural similarity. In particular, the composition of the Substance indicates [redacted]. Source substance (1) consists of [redacted]. Source substance (2) is [redacted]. The [redacted] fraction is likely less bioavailable than [redacted] and the approach therefore conservative.

42 You justify the read-across as "based on similar physical-chemical, toxicokinetic and toxicological properties." According to your hypothesis, "Based on all available data it can be concluded that the target chemical Alcohols, C13-15-branched and linear will be absorbed in a lesser degree than the selected source chemicals reducing the internal exposure. […] To account for the slower metabolism rate of branched compared to linear alcohols, branched isomers were selected as worst case source substances." You provide studies (e.g. OECD TG 422 with the Substance, OECD TG 414 studies with source substances (1) and (2), and OECD TG 408 study with source substance (2)), whose comparison supports your hypothesis and conclusions.

43 ECHA agrees that based on the read-across justification provided and the other information available in the dossier there is a basis for considering the read across plausible. Therefore, you have plausibly demonstrated that relevant properties of the Substance may be predicted from data on the source substance.

44 However, ECHA emphasises that any final determination on the validity of your read-across adaptation will only be possible when the information on the requested study will be available in the dossier and after assessing whether it confirms or undermines the read-across hypothesis.

6.3. Specification of the study design

6.3.1. Species and route selection

45 You did not specify the species to be used for testing. According to the test method OECD TG 443, the rat is the preferred species. Therefore, the study must be conducted in the rat.

46 You did not specify the route for testing. As the test substance is a liquid, the study must be conducted with oral administration of the test substance (Annex X, Section 8.7.2, Column 1).

6.3.2. Pre-mating exposure duration

47 The length of the pre-mating exposure period must be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

48 You did not specify the pre-mating exposure duration for parental (P0) animals.

49 A minimum of 2-week pre-mating exposure duration for P0 animals is sufficient because the full spectrum of parameters on sexual function and fertility will be covered in the F1 animals (Guidance on IRs & CSA, Appendix R.7.6-3). This is because Cohort 1B is extended by mating the Cohort 1B animals to produce the F2 generation (see section 6.3.5. below).

6.3.3. Dose-level setting

50 The aim of the requested test must be to demonstrate whether the classification criteria of the most severe hazard category for sexual function and fertility (Repr. 1B; H360F) and developmental toxicity (Repr. 1B; H360D) under the CLP Regulation apply for the Substance (OECD TG 443, para. 22; OECD GD 151, para. 28; Annex I Section 1.0.1. of REACH and Recital 7, Regulation 2015/282), and whether the Substance meets the criteria for a Substance of very high concern regarding endocrine disruption according to Art.57(f) of REACH as well as supporting the identification of appropriate risk management measures in the chemical safety assessment.

51 To investigate the properties of the Substance for these purposes, the highest dose level must be set on the basis of clear evidence of an adverse effect on sexual function and fertility, but no deaths (i.e., no more than 10% mortality; Annex I, Section 3.7.2.4.4. to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, para. 18) in the P0 animals.

52 In case there are no clear evidence of an adverse effect on sexual function and fertility, the limit dose of at least 1000 mg/kg bw/day or the highest possible dose level not causing severe suffering or deaths in P0 must be used as the highest dose level. A descending sequence of dose levels should be selected to demonstrate any dose-related effect and aiming to establish the lowest dose level as a NOAEL.

53 In summary: Unless limited by the physical/chemical nature of the Substance, the highest dose level in P0 animals must be as follows:

(1) in case of clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, the highest dose level in P0 animals must be determined based on such clear evidence, or
(2) in the absence of such clear evidence, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(3) if there is such clear evidence but the highest dose level set on that basis would cause severe suffering or death, the highest dose level in P0 animals must be set to be the highest possible dose not causing severe suffering or death, or
(4) the highest dose level in P0 animals must follow the limit dose concept.

54 You have to provide a justification with your study results demonstrating that the dose level selection meets the conditions described above.

55 Numerical results (i.e. incidences and magnitudes) and description of the severity of effects at all dose levels from the dose range-finding study/ies must be reported to facilitate the assessment of the dose level section and interpretation of the results of the main study.

6.3.4. Cohorts 1A and 1B

56 Cohorts 1A and 1B belong to the basic study design and must be included.

6.3.4.1. Splenic lymphocyte subpopulation analysis

57 Splenic lymphocyte subpopulation analysis must be conducted in Cohort 1A (OECD TG 443, para. 66; OECD GD 151, Annex Table 1.3).

6.3.4.2. Investigations of sexual maturation

58 To improve the ability to detect rare or low-incidence effects, all F1 animals must be maintained until sexual maturation to ensure that sufficient animals (3/sex/litter/dose) are available for evaluation of balano-preputial separation or vaginal patency (OECD GD 151, para. 12 in conjunction with OECD TG 443, para. 47). For statistical analyses, data on sexual maturation from all evaluated animals/sex/dose must be combined to maximise the statistical power of the study.

6.3.5. Extension of Cohort 1B

59 If the conditions of Annex X, Section 8.7.3., Column 2 are met, Cohort 1B must be extended by mating the Cohort 1B animals to produce the F2 generation.

60 The extension is required, among others, if the use of the Substance is leading to significant exposure of consumers or professionals (column 2, first para., point (a) of Section 8.7.3.) and if there are indications of one or more relevant modes of action related to endocrine disruption from available in vivo studies or non-animal approaches (column 2, first para., point (b), third indent of Section 8.7.3.).

61 The use of the Substance reported in the joint submission is leading to significant exposure of consumers and/or professionals because the Substance is used by consumers and professionals in paints, inks, adhesives (e.g. PROCs 10, 11, 13, 19) as well as in cleaning agents by professionals (e.g. PROCs 10, 11, 13).

62 Furthermore, there are indications of one or more modes of action related to endocrine disruption because changes in organs sensitive to endocrine activity are observed. More specifically, the available OECD TG 408 with analogue substance 2-propylheptan-1-ol (EC No. 233-126-1) shows the following treatment-related histopathological changes:

- Thyroid gland: diffuse follicular hypertrophy, grade 2, observed in 7/10 male rats at 600 mg/kg bw/day;

- Pituitary gland: vacuolation of basophilic (thyrotropic) cells of the glandular part of the pituitary gland, grades 1-3, observed in 3/10 male rats at 600 mg/kg bw/day

63 You have proposed not to include an extension of Cohort 1B.

64 For the reasons stated above, ECHA considers that Cohort 1B must be extended.

65 Organs and tissues of Cohort 1B animals processed to block stage, including those of identified target organs, must be subjected to histopathological investigations (according to OECD TG 443, para. 67 and 72) because there is a concern for reproductive toxicity/endocrine activity indicated by the toxicity-triggers to extend the Cohort 1B.

66 The F2 generation must be followed to weaning allowing assessment of nursing and lactation of the F1 parents and postnatal development of F2 offspring. Investigations for F2 pups must be similar to those requested for F1 pups in OECD TG 443 and described in OECD GD 151.

6.3.6. Cohorts 2A and 2B

67 Annex IX/X, Section 8.7.3., Column 2 provides that the developmental neurotoxicity Cohorts 2A and 2B need to be conducted in case of a particular concern on (developmental) neurotoxicity.

68 Existing information on a substance structurally analogous to the Substance shows evidence of toxicity on the thyroid. Signs of thyroid toxicity rise a particular concern on developmental neurotoxicity (Guidance on IRs & CSA).

69 More specifically, the available OECD TG 408 with analogue substance 2-propylheptan-1-ol (EC No. 233-126-1) shows the following treatment-related histopathological changes:

- Thyroid gland: diffuse follicular hypertrophy, grade 2, observed in 7/10 male rats at 600 mg/kg bw/day.

70 You proposed not to include Cohort 2A and 2B.

71 For the reasons stated above, the developmental neurotoxicity Cohorts 2A and 2B must be conducted.

6.4. Outcome

72 Under Article 40(3)(b) your testing proposal is accepted under modified conditions, and you are requested to conduct the test with analogue substance isotridecan-1-ol (EC No. 248-469-2), as specified above.

6.4.1. Further expansion of the study design

73 No triggers for the inclusion of Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including Cohort 3 if relevant information becomes available from other studies or during conduct of this study. Inclusion is justified if the available information meets the criteria and conditions which are described in Column 2, Section 8.7.3., Annex IX/X. You may also expand the study due to other scientific reasons in order to avoid a conduct of a new study. The study design, including any added expansions, must be fully justified and documented. Further detailed guidance on study design and triggers is provided in Guidance on IRs & CSA, Section R.7.6.

74 In your comments you agree to conduct the study.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 31 August 2022, following the necessary clarifications, namely the submission of the Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) which is relevant for your read-across approach where you intend to use an extended one-generation reproductive toxicity study conducted with analogue substance isotridecan-1-ol (EC No. 248-469-2) to fulfil the respective information requirement for the Substance.

ECHA held a third-party consultation for the testing proposal(s) from 31 January 2023 until 17 March 2023. ECHA did not receive information from third parties.

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 took into account your comments and did not amend the request(s) or the deadline.

In the comments to the draft decision, you requested an extension of the deadline for long-term toxicity testing on aquatic invertebrates and long-term toxicity testing on fish from 24 to 30 months from the date of adoption of the decision. You justified the request for additional time required to complete the testing due to an extreme limitation on lab capacity for OECD 211 and OECD 210. ECHA already exceptionally extended by 12 months the deadline from the standard deadline due to this same reason. Furthermore, the dossier indicates that OECD TG 211 study is ongoing with a final report expected by the end of first quarter in 2023. 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: 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 Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

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

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

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 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)

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

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[3].

2. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e., knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[3] https://echa.europa.eu/manuals