~~Confidential~~

Helsinki, 12 October 2023

Addressees
Registrant(s) of 271-231-4 Joint Subm. EM Lead as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
12/09/2018

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C7-9-iso-, C8-rich
EC/List number: 271-231-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***19 July 2027***.

Requested information must be generated using the Substance unless otherwise specified.

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

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) by orals route, in rats, specified as follows:
   – Ten 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. The reporting of the study must provide the justification for the setting of the dose levels;
   – Cohort 1A (Reproductive toxicity);
   – Cohort 1B (Reproductive toxicity) **without** extension to mate the Cohort 1B animals to produce the F2 generation;

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

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

information requirements.

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Assessment of the read-across approach

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

- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

In addition, you have supported other adaptations with data from substances other than the Substance for these standard information requirements:

- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

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

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. 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): *"Members of the Exxal group of alcohols"*

7 You provide the following reasoning for the prediction of toxicological properties: "similar chemical structure, manufacturing process, physicochemical properties and the same type of biological effects or trends among each of these substances".

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.

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

0.1.1.1. Missing supporting information to compare 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 bridging studies to compare properties of the Substance and source substances.

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

13 For the source substances, you provide the studies used in the prediction in the registration dossier. Apart from those 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 it causes the same type of effects as the source substances, for information requirements (endpoints) that you adapt via grouping and read-across. This is relevant in particular for toxicity to reproduction and development.

14 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. Comments to the draft decision

15 In your comments to the draft decision you explain that to substantiate your read-across approach your will apply a phased approach to testing. You agree to testing the Substance. Reproductive and developmental endpoint studies will first be conducted on Exxal 8 (low end of carbon distribution) and bridging studies will be conducted on the intermediary substances (Exxal 9 and 10). The data from phase 1 will be assessed against the read-across hypothesis to inform actions in phase 2 (i.e., read-across hypothesis is valid or additional data generation is warranted).

16 As this strategy relies on a category approach that has not yet been fully described and justified, as well as on data which is yet to be generated for the proposed category members (including bridging studies and supporting information), no conclusion on the compliance of proposed adaptations for category members can be made. You remain responsible for complying with this decision by the set deadline.

0.1.3. Conclusion on the read-across approach

17 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 X of REACH

1. Pre-natal developmental toxicity study in a second species

18 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X, Section 8.7.2.

1.1. Information provided

19 You have adapted this information requirement by using Annex XI, Section 1.5 grouping and read-across. To support the adaptation, you have provided following information:

i. "*Members of the Exxal group of alcohols are currently undergoing testing as part of an integrated testing strategy as agreed upon by ECHA (decision number CCH-D-2114342397-45-01/F) and we are awaiting the results to inform further testing.*"

1.2. Assessment of the information provided

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

1.2.1. Read-across adaptation rejected

21 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.

22 In any case, the registration dossier mentions only an intent to adapt on the basis of future data; which, in the absence of current data, is insufficient to fulfil the requirements of Annex XI, Section 1.5.

23 Therefore, the information requirement is not fulfilled.

1.3. Comments on the draft decision

24 In your comments to the draft decision you agree to perform the requested study.

1.4. Specification of the study design

25 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species. The study in the first species was carried out by using a rodent species (rat).

26 Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

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

28 Based on the above, the study must be conducted in rabbits with oral administration of the Substance.

2. Extended one-generation reproductive toxicity study

29 An extended one-generation reproductive toxicity (EOGRT) study (OECD TG 443) is an information requirement under Annex X, Section 8.7.3. Furthermore column 2 defines the conditions under which the study design needs to be expanded.

2.1. Information provided

30 Although you have not qualified the legal basis of your adaptation, ECHA understands from the provided information that you have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2. You have provided several pieces of information, of which the repeated dose toxicity studies were provided in a IUCLID section other than for the information requirement:

(i) sub-chronic toxicity study (OECD TG 408) 2018 with the Substance

(ii) sub-chronic toxicity study (OECD TG 408) 2018 with the source substance Branched alcohols C11-C14-iso, C13-rich (EC 271-235-6)

(iii) pre-natal developmental toxicity study in rats (OECD TG 414) 2020 with the Substance

31 To support your adaptation, you have also provided the following statements:

(iv) *"At this time it is expected that isooctanol will not be a reproductive toxicant. A one-generation study in rats ([redacted], 1992) was performed with the analog substance 1-dodecanol (CAS RN 112-53-8) using the Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test protocol. Male and female rats were administered 1-dodecanol orally via the feed at doses of 100, 500 and 2000 mg/kg/day for a period of 14 days. No effects were seen on reproductive or developmental parameters up to doses of 2000 mg/kg/day. 1-Dodecanol at the dose administered had no influence on body weight, weight gain, food consumption and reproductive efficiency in the parental generation. Pregnancy rates were not statistically altered and there were no differences in the lengths of the gestation periods. No organ toxicity was observed in the females, a nd there was no effect on the number of pups per litter, weight, sex ratio, or mortality rate from Days 1 to 5 after birth.*

(v) *Data collected from analogue substances used for read-across in subchronic 90-day studies (Isooctanol, 68526-83-0; Isotridecanol, 68526-86-3) provide evidence of lack of effects on spermatogenesis parameters, and provide no indication of neurotoxicity or immunotoxicity based on clinical chemistry parameters and organ weights. If the decision is made to run an EOGRTS study, this data would allow justification for a shortened premating dosing period (shortened from standard 10-week window to a 2-week dosing period) as well as a lack of justification for including cohorts 2A and 2B.*

(vi) *We will also be evaluating PNDT information to inform justification for this endpoint. Furt her test data that will be collected as part of the integrated testing strategy as agreed upon by ECHA (decision number CCH-D-2114342397-45-01/F) are outlined in the assessment reports and will be used to inform the justification for this endpoint."*

32 The information provided in statement (iv) cannot be taken into account in the assessment of your weight of evidence adaptation because the studies they refer to are not actual sources of information in the form of robust study summaries, as required under Article 10(a)(vi) and (vii).

2.2. Assessment of the information provided

33 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

34 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

35 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

36 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

37 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

38 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

39 The common deficiencies are set out here, while the specific ones are set out under the information requirement concerned in the Sections below.

40 Relevant information that can be used to support weight of evidence adaptation for the information requirement of Annex X, Section 8.7.3 includes similar information that is produced by the OECD TG 443 with a design as specified in this decision. OECD TG 443 requires the study to investigate the following key elements: A) sexual function and fertility, B) toxicity to offspring, and C) systemic toxicity.

A) Sexual function and fertility

41 Sexual function and fertility on both sexes must include information on mating, fertility, gestation (length), maintenance of pregnancy (abortions, total resorptions), parturition, lactation, organ weights and histopathology of reproductive organs and tissues, litter sizes, nursing performance and other potential aspects of sexual function and fertility.

42 The studies (i.-iii.) you submitted provide limited information on sexual function and fertility. More specifically, they provide information only on oestrous cyclicity and sperm parameters and they do not inform on mating performance and gestation length of pre-exposed animals, parturition, lactation, litter sizes, nursing performance and other potential aspects of sexual function and fertility. The study iii. gives information on maintenance of pregnancy (abortions, total resorptions) limited to not pre-exposed parental animals.

43 Furthermore, the reliability of stuy ii. is significantly affected by the deficiencies explained in Section 0.1.

B) Toxicity to offspring

44 Information on pre- and perinatal developmental toxicity is reflected by litter sizes, postimplantation loss (resorptions and dead foetuses), stillborns, and external malformations; postnatal developmental toxicity is reflected by survival, clinical signs and body weights of the pups (or litters), and other potential aspects related to pre-, peri- and postnatal developmental toxicity observed up to postnatal day 13.

45 Study iii. provides information on pre-natal developmental toxicity to offspring. None of the studies (i-iii) provide information on developmental toxicity observed up to postnatal day 13.

46 Furthermore, the reliability of stuy ii. is significantly affected by the deficiencies explained in Section 0.1.

C) Systemic toxicity

47 Information on systemic toxicity include clinical signs, survival, body weights, food consumption, haematology, clinical chemistry, organ weights and histopathology of non-reproductive organs and other potential aspects of systemic toxicity in the parental generation up to postnatal day 13.

48 Studies i. and ii. provide relevant information on systemic toxicity, whereas study iii. provides only limited information on systemic toxicity.

49 Furthermore, the reliability of stuy ii. is significantly affected by the deficiencies explained in Section 0.1.

Conclusion

50 Taken together, the sources of information, as indicated above, provide information on reproductive and systemic toxicity, but essential parts of information of the hazardous property is lacking, including information on: mating, gestation (length), maintenance of pregnancy (abortions, total resorptions), parturition, lactation, litter sizes, nursing performance and other potential aspects of sexual function and fertility; and toxicity to offspring. Furthermore, one source of information is unreliable due to deficiencies identified in Section 0.1.

51 Therefore, it is not possible to conclude based on any source of information alone or considered together, whether your Substance has the particular (hazardous) properties.

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

2.3. Comments on the draft decision

53 In your comments to the draft decision you agree to perform the requested study. You disagree however with the dose setting principles described above, and explain that you find a top dose of 700 mg/kg bw and day appropriate based on available data.

2.4. Specification of the study design

2.4.1. Species and route selection

54 A study according to the test method OECD TG 443 must be performed in rats with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

2.4.2. Pre-mating exposure duration

55 The length of 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.

56 Ten weeks pre-mating exposure duration is required to obtain results adequate for classification and labelling and/or risk assessment. There is no substance specific information in the dossier supporting shorter premating exposure duration (Guidance on IRs and CSA, Section R.7.6.).

57 Therefore, the requested pre-mating exposure duration is ten weeks.

2.4.3. Dose-level setting

58 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, paragraph 22; OECD GD 151, paragraph 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.

59 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; Section 3.7.2.4.4 of Annex I to the CLP Regulation) or severe suffering such as persistent pain and distress (OECD GD 19, paragraph 18) in the P0 animals.

60 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.

61 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.

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

63 In your comments on the draft decision, you describe that "*toxicokinetic studies revealed evidence of dose-dependent saturation of kinetic processes at doses greater than 700 mg/kg bw/day, which was the basis for the choice of top dose in the subchronic study on Exxal 8. In addition, evidence of systemic toxicity was noted at this dose..*".

64 With respect to your dose level selection rationale, it is the responsibility of the study sponsor and the test laboratory to derive adequate dose levels in line with section 5.3.3 of this decision. Please also refer to the published advice on dose level selection for reproductive toxicity studies (https://echa.europa.eu/-/new-advice-for-determining-dose-

levels-in-toxicity-testingTests). Under REACH, tests on substances are required to generate information on the intrinsic properties of substances. If the intrinsic property of the Substance is a non-linear increase in toxicokinetic parameters (e.g. bioavailability), then this is a crucial intrinsic property of the Substance and the toxicological consequences of this intrinsic property need to be investigated in the requested studies. Therefore, the observation of a potential saturation of metabolic pathways alone cannot be used to limit the highest dose and should even be considered as further reason to test higher in this case; because the effects seen at lower doses cannot be extrapolated linearly.

65 For dose-level selection, it is also important to rely on adequate information to perform the EOGRT study. In this case, you rely for dose level setting on a 14-day toxicokinetic study and a 90-day repeated dose study which were performed without considering important life stages such as mating, gestation, parturition and lactation. Therefore, you lack crucial information to decide on adequate dose levels for adequately designing an EOGRT study. Therefore, ECHA strongly recommends to conduct a suitable dose-range finding study such as an OECD TG 422 study before deciding on the dose levels for the EOGRT study.

66 With regard to the systemic effects observed at 700 mg/kg/day, ECHA concludes that these do not meet the requirement stated in paragraph 59, because they are not "clear evidence of an adverse effect on sexual function and fertility".

67 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.

2.4.4. Cohorts 1A and 1B

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

2.4.4.1. Histopathological investigations in Cohorts 1A and 1B

69 In addition to histopathological investigations of cohorts 1A, 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, paragraph 67 and 72) if

- the results from Cohort 1A are equivocal,
- the test substance is a suspected reproductive toxicant or
- the test substance is a suspected endocrine toxicant.

2.4.4.2. Splenic lymphocyte subpopulation analysis

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

2.4.4.3. Investigations of sexual maturation

71 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, paragraph 12 in conjunction with OECD TG 443, paragraph 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.

2.4.4.4. Further expansion of the study design

72 The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort

3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or 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 Annex IX/X, Section 8.7.3., Column 2. 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.

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

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

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

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

The compliance check was initiated on 17 January 2022.

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) but extended the deadline.

In your comments, you requested an extension of the deadline. The deadline of the draft decision was set based on standard practice for carrying out OECD TG tests. However, 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 and aligning with the category members.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressees of this decision and their corresponding information requirements

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

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

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

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.

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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.

Information on the Test Material needed in the updated dossier

a) 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.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP

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

(ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex) and Annex XI Section 1.5 of REACH; namely all the constituents must be identified as far as possible as well as their concentration and the variability in these concentrations. 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).