

Helsinki, 30 May 2024

Addressee(s)

Registrants of JS_33703-08-1 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision

29 March 2023

Registered substance subject to this decision ("the Substance")

Substance name: Diisononyl adipate

EC number: 251-646-7

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 **10 February 2027**.

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

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

1. Long-term toxicity testing on fish with the analogue substance bis(2-ethylhexyl) adipate (EC 203-090-1) 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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210) with the analogue substance bis(2-ethylhexyl) adipate (EC 203-090-1).

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.

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.

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.

Authorised¹ 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)

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Reasons related to the information under Annex VIII of REACH**1. Long-term toxicity testing on fish**

1 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.

1.1. Triggering of the information requirement

2 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.

3 Under Section 4.8 of your technical dossier, you have provided an EU Method A.6 study. The saturation concentration of the Substance in water was determined to be of <0.1 mg/L. You indicate that in that study the detection limit of this substance was reached and as there is no literature value for the Substance available, you use a value of 0.0032 mg/L from a structural analogue substance (Bis(2-ethylhexyl) adipate (CAS 103-23-1) that is also the proposed source substance for the long-term toxicity testing for fish.

4 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

5 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 2.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on fish

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

2.1. Information provided

7 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test according to OECD TG 210 with the analogue substance bis(2-ethylhexyl) adipate (EC 203-090-1).

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

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

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

2.2. Assessment of the read-across approach

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

2.2.1. Read-across adaptation

12 You seek to adapt this information requirement by using a grouping and read-across approach under Annex XI, Section 1.5.

13 You provide a read-across justification document "[REDACTED]" in Section 13 of your technical dossier.

2.2.2. Identification of source substances and read-across hypothesis

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

- bis(2-ethylhexyl) adipate, EC 203-090-1.

15 You provide the following hypothesis for read across for the prediction of toxicological properties: *"the structl of the source and target is similar as they are both adipic esters. Their comparable structural characteristics and functional groups lead to similar physico-chemical and toxicological properties.of the source and target substances. The similarity of the (eco)-toxicological effects is based on: poor water solubility (<1 mg/l), lipophicity (log Kow >5) and ready biodegradation (>90% in 28 d)".*

16 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.

2.2.3. Assessment of the read-across hypothesis

17 The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by you are appropriate to fulfil the

relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting, wherever possible, the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

- 18 Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".
- 19 The first Recital and the first Article of the REACH Regulation establish the "promotion of alternative methods for assessment of hazards of substances" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether it is possible to reliably predict the relevant properties of the substance subject to the present decision by using the results of the proposed tests conducted with the proposed analogue substance (i.e. source substance 1). This means that ECHA considers whether the read-across hypothesis is plausible, based on the information currently available.
- 20 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.
- 21 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.
- 22 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).
- 23 You have based the read across on the structural similarity (common structure and functional groups) of the source and target substance. Therefore you expect the same type of ecotoxicological effects based on common underlying mechanisms. You support your prediction of the source substance's suitability for predicting the long-term toxicity on fish with physico-chemical and ecotoxicological data on the substances as well as QSAR calculations presented in the Read Across Hypothesis and Justification for Diisononyl Adipate document.
- 24 ECHA has assessed the information provided in the Substance dossier, the Read Across Hypothesis and Justification document and agrees that the Substance and the source substance:
- are structurally similar adipic acid esters with the difference being that the Substance has two isononyl residues instead of of hexyl chains branching at the second carbon atom with ethyl side chains;
 - the structural similarity is likely to lead to similar physico-chemical and toxicological properties;
 - are poorly water soluble (<0.1 mg/L), highly lipophilic (log Kow >8), highly adsorptive (log Koc >4) and readily biodegradable;
 - do not contain impurities that would be relevant for the aquatic toxicity testing.
- 25 In addition, the available short-term bridging studies indicate low aquatic toxicity both to aquatic invertebrates and fish.

2.2.4. Conclusion

- 26 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 hypothesis of your read across approach plausible. Therefore, you have plausibly demonstrated that relevant properties of the Substance may be predicted from data on the analogue substance. However, ECHA emphasises that any final determination on the validity of your read-across approach and adaptation of the information requirement will only be possible when the information on the requested study will be available in the dossier.
- 27 Based on the above, you have established that it is possible to reliably predict the long-term toxicity to fish of the Substance from data on the source substance. Your read-across approach under Annex XI, Section 1.5. is accepted.

2.3. Test selection and study specifications

- 28 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.).
- 29 The source substance is difficult to test due to the low water solubility (0.0032 mg/L by EU Method A.6 and adsorptive properties (log Kow 4.56 by KOCWIN Program V2.00). OECD TG 210 specify 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 210. 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.
- 30 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).
- 31 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.

2.4. Outcome

- 32 Your read across testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test, as specified above.
- 33 In the comments to the draft decision, you agree to perform the requested 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 (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 4 April 2023.

ECHA held a third party consultation for the testing proposal(s) from 3 May 2023 until 19 June 2023. ECHA did not receive information from third parties.

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

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

ECHA did not receive any comments within the notification 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: 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, with the corresponding requests in this decision provided within parenthesis:

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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

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

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1 Test methods, GLP requirements and reporting

- (1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
- (2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
- (3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (<https://echa.europa.eu/practical-guides>).
- (4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

- (1) Selection of the Test material(s)

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

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- its representativeness towards the specified analogue substance,
- it supports the read-across prediction as presented in the read-across justification document,
- the impact of each constituent on the test results for the endpoint to be assessed. For example, if a constituent/group of constituents of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/group of constituents.

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

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.

- The reported composition must include the careful identification and description of the characteristics of the Test Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.
- The reported composition must include other parameters relevant for the property to be tested, in this case.

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>).