~~Confidential~~

Helsinki, 13 February 2024

Addressee(s)
Registrant(s) of JS_51566-62-2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
28 July 2021

Registered substance subject to this decision ("the Substance")
Substance name: 3,7-dimethyloct-6-enenitrile
EC/List number: 257-288-8

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 ***21 May 2026***.

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

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

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

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

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.
You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Contents

Reasons common to several requests

0. Substance-tailored exposure-driven testing adaptation rejected

1 In your comments to the draft decision, you indicate your intention to adapt the following information requirements based on exposure considerations, according to Annex XI, Section 3 of REACH regulation:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.);
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6).

0.1. Assessment of the information provided

0.1.1. Substance-tailored exposure-driven testing adaptation rejected

2 A substance-tailored exposure-driven testing adaptation must fulfil the cumulative conditions set out under Annex XI, Sections 3(1) as well as 3(2)(a), (b) or (c).

3 You have provided the same information for both information requirements listed above. ECHA understands that you intend to adapt these information requirements according to Annex XI, Section 3.2 (a) substance-tailored exposure-driven testing.

0.1.1.1. Exposure always well below PNEC not demonstrated

4 The results of the exposure assessment must show that exposures are always well below the PNEC, i.e. risk characterisation ratios (RCRs) must always be well below 1. This means that a high level of confidence is needed to demonstrate that every RCR is low enough to ensure that the risks are always controlled, under every plausible condition of the manufacture and all identified uses of the Substance. For this purpose, the possible sources of variability and uncertainty must be considered in the assessment of exposure (Guidance on IRs and CSA Chapter R.16, page 68).

5 Uncertainty must be taken into account, either by carrying out the environmental exposure assessment using conservative assumptions and default values, which are provided in Guidance on IRs and CSA Chapters R.16. (Guidance on IRs and CSA Chapter R.19).

6 Alternatively, when the environmental exposure assessment is not based on these generic assumptions, a stepwise, tiered approach including an uncertainty analysis must be conducted. This analysis can be qualitative, deterministic, or probabilistic, to demonstrate that the risk is adequately controlled (Guidance on IRs and CSA Chapter R.19 provides a framework for carrying out a stepwise, tiered approach to uncertainty analysis). The results must be provided in the dossier to demonstrate that the application of such tiered uncertainty analysis gives a clear indication that the risk is adequately controlled (e.g. an increased belief that the (distribution of the) RCR is less than 1).

7 You have provided an exposure assessment reporting 8 exposure scenarios (ES) with quantitative exposure assessment and risk characterisation for each of them.

8 Most exposure assessments are not based on the generic assumptions recommended in Guidance on IRs and CSA Chapter R.16, but you have used input parameters from specific environmental release categories (SpERC) developed by AISE or by IFRA instead. For example, the background documentation from AISE explains that:

- "*Different approaches and information sources were consulted in this background document, sometimes in a weight of evidence approach, to derive the most appropriate and representative release factors. These approaches include 1) extraction of release factors from literature, 2) data collected of cross-*

checks done in the sector, and 3) qualitative argumentation based on thorough process and plant operations management understanding. Scaling (read-across) was also used to bridge between different plant sizes";

- "*Normally, an (average) realistic worst-case value was taken from the whole of data pool collected. In addition, and more generally, the use of historical emission information for the RF derivation may contribute to conservatism because those emissions are likely higher than current emissions as a result of ongoing innovation and regulation, thus increasing process efficiency and emission reductions over time (Reihlen et al, 2016). It can be assumed some literature date (e.g. from US-EPA collected in the seventies), are not fully representative anymore, and in a final evaluation more weight was generally given to the most recent data*".

9 AISE's explanation speculates that the input values are "*normally*" worst-case or conservative values, but the information provided is insufficient to independently verify that the resulting exposure assessment and the calculated PEC are conservative enough and cover all the possible sources of variability and uncertainty.

10 Using the default input parameters recommended in the Guidance on IRs and CSA, Section R.16, RCR values higher than those presented in your CSR can be calculated, in several cases higher than 1.

11 You have not provided results of the uncertainty analysis for the environmental exposure assessment ensuring a high level of confidence that the risk is always adequately controlled. Potential sources of variability and uncertainty under every plausible condition of uses of the Substance have not been presented. Therefore, it is not possible to conclude that the risks are adequately controlled, and the information provided in the CSR is regarded as inadequate to support the exposure-based adaptations.

12 On this basis, you have not demonstrated that your exposure assessment is always conservative enough, nor have demonstrated that worst case conditions are covered by the modified parameters introduced in your risk assessment. Therefore, the RCRs cannot be regarded as being well below 1 for most of the exposure scenarios presented. Thus, it is not possible to conclude that the risks are adequately controlled and exposures cannot be regarded as being always well below the PNEC.

0.1.1.2. Lack of or incomplete exposure assessment for one member

13 Under Annex XI, Sections 3(1) and (2), testing may be omitted based on the exposure scenario(s) developed in the chemical safety report (CSR) by providing an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment.

14 In the comments to the draft decision you indicate that the comments were provided on behalf of all registrants, recipients of the draft decision and provide an overview of the risk characterisation further referring to the attached CSR.

15 ECHA notes that based on the information submitted in REACH-IT, the CSR is not jointlu submitted in the joint submission. Therefore it is not clear if exposure scenario(s) provided in the comments also apply to other member(s) of the joint submission.

16 In any event, ECHA notes that the registration dossier of one member registrant does not currently include an exposure assessment. In addition, RCR values higher than 1 can be calculated for the uses reported in the registration dossier of that member registrant using the corresponding default input parameters recommended in Guidance on IRs and CSA R.16.

17 Therefore an adequate and scientifically supported justification has not been provided.

0.2. Conclusion on the substance-tailored exposure driven testing adaptation

18 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected for the information requirements long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) and long-term toxicity testing on fish (Annex IX, Section 9.1.6).

Reasons related to the information under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

20 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing in fish shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of 3,7-dimethyloctan-1-ol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT orvPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The chemical safety assessment provided in the CSR (chapter 13) reveals, that all identified uses are safe under the given refinements. Therefore, and for reasons of animal welfare,a long-term testing in fish is not provided."*;

1.2. Assessment of the information provided

21 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5. (see the amendment of REACH by the Commission Regulation (EU) 2022/477 of 24 March 2022).

22 Your adaptation is therefore rejected and the information requirement is not fulfilled.

23 In your comments to the draft decision you agree with the issues identified above however, you indicate your intention to fulfil this information requirement according to Annex XI, Section 3 of the REACH Regulation.

24 As explained in the section 'Reasons common to several requests' above, your new adaptation as presented in your comments is rejected. Therefore, you remain responsible for complying with this decision by the set deadline.

2. 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.).

2.1. Information provided

26 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing in invertebrates shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on invertebrates. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets*

the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of 3,7-dimethyloctan-1-ol reveals neither a need to classify the substance as dangerous to the environment, nor is it a PBT orvPvB substance, nor are there any further indications that the substance may be hazardous to the environment. The chemical safety assessment provided in the CSR (chapter 13) reveals, that all identified uses are safe under the given refinements. Therefore, and for reasons of animal welfare,a long-term testing in fish is not provided.".

2.2. Assessment of the information provided

27 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6. (see the amendment of REACH by the Commission Regulation (EU) 2022/477 of 24 March 2022).

28 Your adaptation is therefore rejected and the information requirement is not fulfilled.

29 In your comments to the draft decision you agree with the issues identified above however, you indicate your intention to fulfil this information requirement according to Annex XI, Section 3 of REACH Regulation.

30 As explained in the section 'Reasons common to several requests' above, your new adaptation as presented in your comments is rejected. Therefore, you remain responsible for complying with this decision by the set deadline.

2.3. Study design

31 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

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

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 23 August 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 requests.

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

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

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

Appendix 3: Addressee(s) of this decision and their corresponding information requirements

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

- the information specified in 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 (https://echa.europa.eu/practical-guides).

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

1.2 Test material

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

(1) Selection of the Test material(s)

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

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

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

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

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