~~Confidential~~

Helsinki, 02 November 2023

Addressee(s)
Registrant of 919-489-5 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
03 September 2018

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of (2E)-Tridec-2-enenitrile and (2Z)-Tridec-2-enenitrile and (3E)-Tridec-3-enenitrile and (3Z)-Tridec-3-enenitrile
EC/List number: 919-489-5

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 ***11 May 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 (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211).

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

2. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; 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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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)

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Reasons 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

2 In the provided OECD TG 105 study (2015), the saturation concentration of the Substance in water was determined to be 0.27 mg/L.

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

4 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance. In your comments on the draft decision you state that you do not consider the water solubility alone to trigger this information requirement and the draft decision does not address why the data set for short-term toxicity does not provide a true measure of the intrinsic aquatic toxicity.

5 Please note that poorly water soluble substances require longer time to reach steady-state conditions (Guidance on IRs & CSA, Chapter R.7.8.5 and R.7.8.10.3.). 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 as set out in the legal text (Annex VII, Column 2, Section 9.1.1).

6 In the absence of information on long-term toxicity on aquatic invertebrates, this information requirement is not fulfilled.

7 In your comments on the draft decision, you also provided additional arguments on why you consider that the required information is not necessary. You provide arguments in relation to PNEC derivation based on the acute aquatic toxicity data. In addition you describe some challenges in testing the Substance due to low water solubility and development of sensitive analytical methods.

8 On this basis, ECHA understands that you intend to adapt the information requirement by 1) an exposure-based adaptation under Annex XI, Section 3.2 (a), and 2) technical feasibility under Annex XI, Section 2.

9 Your arguments related to the classification and PBT assessment of the Substance as well as animal welfare considerations are addressed further below.

1.2. Assessment of the adaptations provided in the comments

1.2.1. Substance-tailored exposure-driven testing adaptation rejected

10 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).

11 Under Annex XI, Section 3.2(a)(ii), a relevant and appropriate predicted no effect concentration (PNEC) must be derived.

12 For the reasons explained above under this request and request 2, due to the poor solubility of the Substance the provided short-term toxicity data is unlikely to provide a true measure of the toxicity of the Substance. Therefore, your dossier does not include reliable information on the hazardous properties of the Substance on at least three trophic levels (Guidance on IRs and CSA, Section 7.8.5.3).

13 Therefore, you have not demonstrated that an appropriate PNEC can be derived.

14 Based on the above, your substance-tailored exposure driven testing adaptation under Annex XI, Section 3. is rejected.

1.2.2. Adaptation on the basis of testing is technically not possible rejected

15 Under Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance.

16 You claim that the study would be difficult to conduct, however you do not provide evidence to demonstrate that it was technically not feasible which is a different legal criteria.

17 Therefore, your adaptation is rejected.

1.2.3. Your justification to omit the study has no legal basis

18 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

19 Your justification refers to animal welfare considerations, classification and PBT assessment. These justifications to omit this information do not refer to any legal ground for adaptation under Annex XI to REACH.

20 Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing, classification and PBT assessment are not on their own a legal ground for adaptation under the general rules of Annex XI.

1.3. Study design

21 The Substance is difficult to test due to the low water solubility (0.27 mg/L), adsorptive (Log K_{ow} above 6) and volatility properties (Henry's Law constant of 7876.3 Pa m3/mol). The OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in the 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 the 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 solution.

Reasons related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

22 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

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

24 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

25 In the absence of information on long-term toxicity on fish, this information requirement is not fulfilled.

26 Therefore, the information requirement is not fulfilled.

27 Your comments on the draft decision for this information requirement are the same as for request 1. They are described and addressed above under request 1.

2.2. Study design

28 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.).

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

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.

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.

In your comments to the draft decision, you requested an extension of the deadline to provide the requested information due to limited lab capacity and proposed tiered testing allowing to consider using the long-term daphnia study (Request 1) as a basis of setting the threshold concentration in the long-term fish study (Request 2). You provided a letter from Noack Laboratorien to support the arguments regarding lab capacity.

On this basis, ECHA has extended the deadline from 24 to 30 months.

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 and VIII to REACH, for registration at 10-100 tpa;

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

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

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1 Test methods, GLP requirements and reporting

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

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

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).

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

1.2 Test material

(1) Selection of the Test material(s)

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

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

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

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

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

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