

Helsinki, 4 June 2021

**Addressees**

Registrants of EC264-867-9 listed in the last Appendix of this decision

**Date of submission of the dossier subject of a decision**

14/03/2019

**Registered substance subject to this decision, hereafter 'the Substance'**

Substance name: Dodecenylsuccinic acid, compound with 2,2',2''-nitrioltriethanol (1:1)

EC number: 264-867-9

CAS number: 64396-12-9

**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)**

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **13 June 2022**.

The requested information must be generated using the Substance unless otherwise specified.

**A. Information required from 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 9.1.6.1.; test method OECD TG 210).

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annexes IX of REACH".

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

**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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

### **Appeal**

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: <http://echa.europa.eu/regulations/appeals>.

Approved<sup>1</sup> under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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<sup>1</sup> 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 A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposal you submitted.

### 1. Long-term toxicity testing on aquatic invertebrates

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

#### 1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for long-term toxicity testing on aquatic invertebrates according to OECD TG 211 (Daphnia magna Reproduction Test).

The current registration dossier does not contain information on long-term toxicity testing on aquatic invertebrates for the Substance. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

In your comments you add that *"This non-vertebrate data is helpful in understanding of environmental impact. It may be necessary to perform this study, but it is proposed to first check biotic and abiotic changes that could be found in a prolonged biodegradation assay."*

ECHA understands that you are considering replacing the proposed study with application of a read across adaptation. However, you have not provided any hypothesis substantiating a read across adaptation and therefore ECHA cannot assess whether this adaptation would remove the real information need.

#### 1.2. Test selection and study specifications

The proposed long-term toxicity testing on aquatic invertebrates (test method: OECD TG 211) is appropriate (ECHA Guidance R.7.8.4.1.).

#### 1.3. Outcome

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

#### *Study design*

The Substance is difficult to test as it is ionisable (pKa1 of 6.2 and pKa2 of 8) and surface active (surface tension of 22.7 mN/m). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

## 2. Long-term toxicity testing on fish

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require you to carry out additional tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI. Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

### 1.1. Information provided to fulfil the information requirement

In your dossier you have provided the following justification to omit the study: *"the substance rapidly biodegrades and appears to be of low toxicity and furthermore Invertebrates appear to be more sensitive organisms than fish so that further animal testing is not justified"*.

We have assessed this information and identified the following issue:

You have not provided any legal basis for the adaptation and it is unclear under which legal ground specified under Annex XI to REACH your justification would be related to. In any case, the claim that invertebrates appear to be more sensitive organisms than fish is not based on compelling evidence as short-term aquatic toxicity studies are not reliable (as specified in a separate draft compliance check decision notified to you).

In your comments on the draft decision you indicate that *"It is considered unethical to perform this animal test prior to further work on invertebrates and until degradation routes in the environment are fully understood. This study may be subsequently important, but a decision is needed in the light of prior test work. The assessment will include review of data on the separate ions / starting materials."*

From this statement, ECHA understands that you are considering replacing the required study with a read across adaptation. However, you have not provided any hypothesis substantiating a read across adaptation and therefore ECHA cannot assess whether this adaptation would remove the real information need.

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

### 1.2. Test selection and study specifications

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

### 1.3. Outcome

Under Article 40(3)(c) and you are requested to conduct the test with the Substance, as specified above.

#### *Study design*

OECD TG 210 specifies that for difficult to test substances 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 Section A.1.

## **Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes**

### **A. 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<sup>2</sup>.

### **B. 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 and other parameters relevant for the property to be tested.

This information is needed to assess 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<sup>3</sup>.

<sup>2</sup> <https://echa.europa.eu/practical-guides>

<sup>3</sup> <https://echa.europa.eu/manuals>

## **Appendix C: General recommendations when conducting and reporting new tests for REACH purposes**

### **A. Environmental testing for substances containing multiple constituents**

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

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

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

**Appendix D: Procedure**

ECHA received your testing proposal(s) on 2 May 2018.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 18 June 2019, following the necessary clarification of the identity of your substance.

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 took into account your comments and did not amend the requests.

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 E: List of references - ECHA Guidance<sup>4</sup> and other supporting documents**Evaluation of available information

Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping

Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)<sup>5</sup>

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)<sup>5</sup>

Physical-chemical properties

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate

Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment

Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing

Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

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<sup>4</sup> <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

<sup>5</sup> <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>



OECD Guidance documents<sup>6</sup>

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

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<sup>6</sup> <http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm>

**Appendix F: Addressees of this decision and the corresponding information requirements applicable to them**

You must provide the information requested in this decision for all REACH Annexes applicable to you.

<b>Registrant Name</b>	<b>Registration number</b>	<b>Highest REACH Annex applicable to you</b>

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.