~~Confidential~~

Helsinki, 2 May 2022

Addressees
Registrants of SCC_334-045_[redacted] Aldehyde L as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
31/05/2021

Registered substance subject to this decision ("the Substance")
Substance name: Dodecanoic acid, 2,2-dimethyl-3-oxopropyl ester
EC number: 468-880-2

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 ***7 August 2024***.

Requested information must be generated using the Substance or its relevant hydrolysis product(s). A justification for the selection of the test material must be provided.

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

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2)

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

2. Long-term toxicity testing on fish 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

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

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

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.

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

Reasons for the decision(s) 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 Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

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. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

3 Under Section 4.8 of your technical dossier, you have provided an estimation of the water solubility for the Substance performed using US EPA EPIWIN WSKOW (version 1.41). The saturation concentration of the Substance in water was determined to be 0.679 mg/L at 25°C.

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

5 The examination of the information provided as well as the selection of the requested test and the test design are addressed under Appendix 1.3.

6 In your comments to the draft decision, you agree to conduct the requested study on the Substance.

Reasons for the decision(s) related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

7 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

8 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. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

9 As already explained in section "1." of this Appendix, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

10 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 in section "4." of this of this Appendix.

11 In your comments to the draft decision, you disagree to conduct the requested study. ECHA is addressing your comments under section "4." of this Appendix.

Reasons for the decision(s) related to the information under Annex IX of REACH

3. Long-term toxicity testing on aquatic invertebrates

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

13 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). You have submitted a testing proposal for long-term testing on fish only. In case there is also a data gap for toxicity to invertebrates, it is necessary to request this information as an additional test to further investigate the effects on aquatic toxicity.

3.1. Information provided to fulfil the information requirement

14 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "Due to the unstable nature of the test substance, it can be assumed that upon contact with water and organic matter, the test item undergoes rapid degradation resulting in the formation of respective degradation products. Therefore, aquatic toxicity is unlikely to occur. Thus, the CSR does not show a need for an additional long-term aquatic test".

15 We have assessed this information and identified the following issue:

16 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

17 Therefore, your adaptation is rejected, and the information requirement is not fulfilled.

18 Therefore, ECHA concludes that an appropriate long-term toxicity study on aquatic invertebrates is needed.

3.2. Test selection and study specifications

19 The Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (Guidance on IRs and CSA, Section R.7.8.4.1.).

20 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.

21 The Substance is difficult to test due to its low water solubility (0.679 mg/L predicted using US EPA EPIWIN WSKOW v 1.41) and high adsorptive properties (log Kow of 7.41 based on OECD TG 117). In addition, you indicate that the Substance hydrolyses rapidly. You must monitor the test concentration(s) of the Substance (and/or its hydrolysis product(s), as relevant) 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 (and/or its hydrolysis product(s) depending on the selected test material) in the test solutions.

3.3. Outcome

22 Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance and/or its hydrolysis product(s), as specified above.

In your comments to the draft decision, you agree to conduct the requested study on the Substance. Your comments on the adequacy of the time set for provision of the information are addressed in Appendix 2 of this decision.

4. Long-term toxicity testing on fish

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

4.1. Information provided to fulfil the information requirement

24 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210).

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

26 ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

27 ECHA did not receive information concerning the testing proposal during the third-party consultation.

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

4.2. Test selection and study specifications

29 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.).

30 OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under Appendix 1.3, the Substance is difficult to test. Therefore, you must fulfil the requirements described in section 3.2, 'Test selection and study specifications', under Appendix 1.3.

4.3. Outcome

31 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above and/or its hydrolysis product(s).

32 In your comments to the draft decision, you refer to the parallel examination of a testing proposal by the UK authorities.

33 ECHA notes that the testing proposal evaluation under REACH is an independent process, and it cannot be aligned with regulatory processes under legislations in non-EEA states. In any case, we also refer to your general comments on the adequacy of time set for provision of the information and ECHA's acceptance of a time extension, addressed in Appendix 2 of this decision.

34 ECHA emphasizes that under REACH, the long-term toxicity testing on fish must be considered if the substance is poorly water soluble. In addition, the environmental hazard assessment which includes classification and labelling and the identification of PNEC, needs to be based on information covering at least species from three trophic levels: algae/aquatic plants, invertebrates (Daphnia preferred), and fish (ECHA Guidance R.7.8.5.3). For substances with low solubility and hydrophobic properties, risks cannot be reliably assessed based on short term toxicity tests (ECHA Guidance R.7.8.4.3). Therefore, for such substances, information on both long-term toxicity to invertebrates and fish needs to be provided for the purpose of the Chemical Safety Assessment.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 23 August 2021.

ECHA held a third-party consultation for the testing proposal(s) from 30 September 2021 until 15 November 2021. 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 took into account your comments and did not amend the requests but amended the deadline.

The timeline indicated in the draft decision to provide the information requested was 12 months from the date of adoption of the decision. In your comments to the draft decision, you requested an extension of the timeline to 24 months. You justified your request by:

- indicating that the requested tests are very complex as it is not known which hydrolysis products are formed. Therefore, the internal tests cannot be completed before mid-June 2022 and the actual toxicity testing cannot be initiated before July 2022.
- referring to documentation from your selected test laboratory that indicates that to carry out the studies for this difficult to test substance in line with the OECD Guidance 23, the laboratory estimates to be able to start the long-term Daphnia test (OECD GD 211) in Q3 2022 and the long-term fish study (OECD GD 210) in Q4.

ECHA agrees that the Substance is difficult to test and the preparatory work for the studies can be time consuming. Based on the provided information, ECHA has extended the deadline to 24 months.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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 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]

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].

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.
- you claim that the Substance hydrolyses rapidly. However, as you have adapted the information requirement on Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.), the DT50 for hydrolysis of the Substance under relevant conditions and the identity of hydrolysis product(s) are not known. In the absence of this critical information, ECHA is not in a position to assess whether the requested studies should be conducted on the Substance or on its relevant hydrolysis products(s). You may consider conducted the requested on the Substance or on its relevant hydrolysis products(s). In any case, adequate justification for the selection of the test material must be provided.

(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.

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

- 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 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[3].

[3] https://echa.europa.eu/manuals