~~Confidential~~

Helsinki, 21 June 2022

Addressees
Registrant(s) of JS_IDOPAA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
06/04/2021

Registered substance subject to this decision ("the Substance")
Substance name: 3-(isodecyloxy)propylammonium acetate
EC number: 249-166-8

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 ***03 January 2024*** *from the date of the decision*.

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

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

1. Stability in organic solvents and identity of relevant degradation products (Annex IX, Section 7.15.; test method: OECD TG 105)

2. Dissociation constant (Annex IX, Section 7.16.; test method OECD TG 112)

3. Viscosity (Annex IX, Section 7.17.; test method OECD TG 114)

4. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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.

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 IX of REACH

1. Stability in organic solvents and identity of relevant degradation products

1 Stability in organic solvents and identity of relevant degradation products is an information requirement under Annex IX to REACH (Section 7.15.).

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for a test on Stability in organic solvent and identity of relevant degradation products (test method: similar to OECD TG 105).

3 Your registration dossier does not include any information on Stability in organic solvents and identity of relevant degradation products.

4 ECHA agrees that an appropriate study on Stability in organic solvent and identity of relevant degradation products is needed.

1.2. Test selection and study specifications

5 As specified in the Guidance on IRs and CSA, Section R.7.1.16.3, there is no generally accepted methodology for performing such stability studies.

6 ECHA considers that the proposed stability test based on a test method similar to OECD TG 105 may be appropriate to cover the information requirement on Stability in organic solvents and identity of relevant degradation products.

1.3. Outcome

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

8 In the comments to the draft decision, you agree to perform the requested study.

2. Dissociation constant

9 Dissociation constant is an information requirement under Annex IX to REACH (Section 7.16.).

2.1. Information provided to fulfil the information requirement

10 You have submitted a testing proposal for a Dissociation constants in water test (test method: OECD TG 112) on the Substance.

11 Your registration dossier does not include any information on Dissociation constant.

12 ECHA agrees that an appropriate study on Dissociation constant is needed.

2.2. Test selection and study specifications

13 The proposed Dissociation constants in water test (test method: OECD TG 112) is appropriate to cover the information requirement on Dissociation constant (ECHA Guidance R.7.1.17.3.).

2.3. Outcome

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

15 In the comments to the draft decision, you agree to perform the requested study.

3. Viscosity

16 Viscosity is an information requirement under Annex IX to REACH (Section 7.17.).

3.1. Information provided to fulfil the information requirement

17 You have submitted a testing proposal for a Viscosity of liquids test (test method: OECD TG 114) on the Substance.

18 Your registration dossier does not include any information on Viscosity.

19 ECHA agrees that an appropriate study on Viscosity is needed.

3.2. Test selection and study specifications

20 The proposed Viscosity of liquids test (test method: OECD TG 114) is appropriate to cover the information requirement on Viscosity (ECHA Guidance R.7.1.18.3.).

3.3. Outcome

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

22 In the comments to the draft decision, you agree to perform the requested study.

4. Pre-natal developmental toxicity study

23 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

4.1. Information provided to fulfil the information requirement

24 You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route with the Substance.

25 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. 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.

26 ECHA agrees that a PNDT study in a first species is necessary.

4.2. Specification of the study design

27 You proposed testing in the rabbit as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

28 You did not specify the route for testing. The oral route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

29 The Substance has a self-classification for Skin Corr. 1B. As stated in the introductory sections of Annexes VII-X of the REACH Regulation: "In vivo testing with corrosive substances at concentration/ dose levels causing corrosivity should be avoided.". Therefore, you shall investigate developmental toxicity using the highest top dose possible that does not cause corrosivity in the gastrointestinal system. You must justify with supporting evidence that the top dose selection and route of administration (dietary vs gavage) is aiming to maximise the systemic toxicity without causing corrosivity. If another route of administration than gavage is chosen, OECD TG 414 demands that the tester should provide explicit justification and reasoning for its selection.

4.3. Outcome

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

31 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).

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 24 June 2021.

ECHA held a third party consultation for the testing proposal(s) from 26 August 2021 until 11 October 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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the modified draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee unanimously agreed on the draft decision in its MSC-78 written procedure. ECHA adopted the decision under Article 51(6) 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:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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;
- 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]

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

(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[3].

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