~~Confidential~~

Helsinki, 25 April 2022

Addressees
Registrant of JS_159034-91-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
01/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: Propylidynetrimethanol, ethoxylated, esters with acrylic acid, reaction products with diethylamine
EC number: 500-425-6

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 ***2 May 2024***.

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

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;

2. 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);

3. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222 OR EU C.32/OECD TG 220 OR C.35/OECD TG 232);

4. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216).

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. Sub-chronic toxicity study (90-days)

1 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

3 ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose 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.

4 ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

5 You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

6 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity; Guidance on IRs and CSA, Section R.7.5.4.3.2.

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. Pre-natal developmental toxicity study

9 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).

2.1. Information provided to fulfil the information requirement

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

11 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.

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

2.2. Specification of the study design

13 You proposed testing in the rat 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.).

14 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

2.3. Outcome

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

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

3. Long-term toxicity testing on terrestrial invertebrates

17 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

18 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 Effects on terrestrial organisms (Section 9.4) at Annex IX requires to provide information on toxicity to invertebrates (Section 9.4.1), effects on soil microorganisms (Section 9.4.2) and on toxicity to plants (Section 9.4.3) for the Substance. You have submitted a testing proposal for effects on soil microorganisms. 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 terrestrial organisms.

3.1. Information provided to fulfil the information requirement

19 Your registration dossier does not include any information on short-term or long-term toxicity on terrestrial invertebrates.

20 Instead, you have adapted this information requirement under the Section 9.4, column 2 of Annex IX with the following justification: "Based on an integrated testing strategy (ITS), the test substance is assigned to soil hazard category 3, according to recommendations of Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment, the registrant proposes to perform the chemical safety assessment based on EPM and to perform a confirmatory long-term study on toxicity to soil microorganisms according to the OECD 216 testing guideline. No further soil toxicity studies are necessary at this step of the ITS".

21 ECHA has assessed this information and identified the following issue:

22 Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focused on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

23 The following information indicates that Substance falls into the soil hazard category 3 (HC3):

- the Substance is not considered very toxic to aquatic organisms;
- the Substance is considered to be highly persistent in soil as it is considered not readily biodegradable based on an OECD 301 D study (6% at 28d, [redacted]., 2012)

24 You have conducted an initial screening assessment based on a $PNEC_{screen}$ estimated using the EPM and a quantitative exposure assessment for the soil compartment (PEC_{soil}). The screening assessment does not indicate a risk for the soil compartment (RCR <1).

25 As specified in the Guidance on IRs and CSA, Table R.7.11-2, for such substance, a confirmatory long-term test on effects to terrestrial organisms from those set out under Annex X, Section 9.4 need to be conducted. The test must be conducted with the most sensitive organism group (if any) as indicated from aquatic toxicity data. Under Guidance on IRs and CSA, Section R.7.11.5.3. in the absence of a clear indication of the most sensitive organism group as indicated by the available aquatic toxicity data, an invertebrate (earthworm or collembolan) test is preferred.

26 Based on the information under Section 6.1. of your technical dossier no sensitivity difference at least by a factor of 10 between aquatic plants, aquatic invertebrates and microorganisms can be established.

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

3.2. Test selection and study specifications

28 The test methods, Earthworm reproduction test (EU C.33/OECD TG 222) or Enchytraeid reproduction test (EU C.32/OECD TG 220) or Collembolan reproduction test in soil (C.35/OECD TG 232) are appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

3.3. Outcome

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

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

4. Effects on soil micro-organisms

31 Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

4.1. Information provided to fulfil the information requirement

32 You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) with the following justification: "This study is considered a long-term toxicity test and will be used as a confirmatory study in the chemical safety assessment for this substance".

33 Your registration dossier does not include any information on effects on soil microorganisms.

34 ECHA assessed this information and has the following comments:

35 As explained in the Guidance on IRs and CSA, Section R.7.11.5.3, in circumstances where less than a full soil toxicity dataset is available, the PNECsoil may be derived from the EPM modified aquatic toxicity data in combination with the necessary confirmatory soil toxicity

test(s) specified in the Guidance on IRs and CSA, Table R.7.11-2. However, where inhibition of sewage sludge microbial activity has been observed, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived.

36 Under Section 6.1. of your technical dossier, you report a study according to OECD TG 209 on the Substance (2013). The 3h-NOEC was determined to be 22 mg/L.

37 As already explained under Appendix 1, Section 3., a long-term toxicity test on terrestrial invertebrates is needed as confirmatory test to the initial screening assessment using the EPM. However, as the Substance shows inhibition to sewage sludge microbial activity, information of Effects on soil micro-organisms is necessary for the purpose of the risk assessment.

38 Therefore, ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

4.2. Test selection and study specifications

Guidance on IRs and CSA, Section R.7.11.3.1. specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

4.3. Outcome

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

40 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 13 July 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.

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 24 months from the date of adoption of the decision. For this purpose, you have provided documentary evidence to support your request.
>
> Based on the evidence provided, ECHA has granted the request and 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 adopted the decision under Article 51(3) 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. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

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

- 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.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.