~~Confidential~~

Helsinki, 26 April 2023

Addressees
Registrants of JS_di-TMPTTA EC 830-217-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/06/2022

Registered substance subject to this decision ("the Substance")
Substance name: Reaction products of acrylic acid with 2,2'-[oxybis(methylene)]bis[2-ethylpropane-1,3-diol]
EC/List number: 830-217-3

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)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***31 January 2025***.

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

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

1. 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)

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

3. Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species)

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 addressee(s) 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

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

1. Long-term toxicity testing on terrestrial invertebrates

1 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.

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for an Earthworm Reproduction Test (EU C.33/OECD TG 222).

3 Your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.

4 ECHA has assessed your testing proposal and notes the following:

5 Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

6 Based on the information from your registration dossier the Substance is potentially very persistent:

- the Substance is considered to be highly persistent in soil as it is considered as not readily biodegradable based on an OECD 301 B study (9% degradation after 29d).

7 On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

8 ECHA agrees that an appropriate long-term toxicity study on terrestrial invertebrates is needed.

1.2. Test selection and study specifications

9 The proposed Earthworm Reproduction Test (EU C.33/OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

1.3. Outcome

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

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

2. Effects on soil micro-organisms

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

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 for Effects on terrestrial organisms at Annex IX covers short-term toxicity to invertebrates (Section 9.4.1.), effects on soil micro-organisms (Section 9.4.2.) and short-term toxicity to plants (Section 9.4.3.). However, you have provided a testing proposal for long-term toxicity to invertebrates only.

2.1. Information provided to fulfil the information requirement

14 Your registration dossier does not include any information on Effects on soil microorganisms, instead you have adapted this information requirement referring to Annex IX, Section 9.4., column 2. To support the adaptation, you have provided the following justification: "As the test substance has a high potential to adsorb to the soil, the test substance belongs to Hazard category 3 as per Table R.7.11—2 in the ECHA guidance R.7c. In the absence of toxicity data under this category, the guidance recommends performing the risk assessment using modified EPM method (i.e., PEC × 10 / PNECscreen) and conducting one confirmatory long-term soil toxicity testing. While an Earthworm reproduction test has been planned with the test substance, the outcome of the chemical safety assessment indicates no risk for the soil compartment (PECx10/PNEC soil <1) suggesting no further requirement for testing for the terrestrial organisms."

2.2. Assessment of the information provided

2.2.1. The adaptation under Annex IX, Section 9.4., column 2 is rejected

15 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 in order to decide the information needed for the chemical safety assessment for the trophic levels which are part of the aquatic toxicity data set (invertebrates, plants). This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM.

16 The intrinsic properties of chemicals on soil microbial communities are not addressed through the EPM extrapolation method because the standard aquatic toxicity data set (i.e. studies on fish, invertebrates and algae) used for derivation of PNEC for aquatic organisms does not include information on toxicity to microbial communities. Therefore, the adaptation possibility based on EPM, as outlined in Annex IX, Section 9.4., Column 2, second paragraph does not apply for the information requirement on Effects on soil micro-organisms.

17 On this basis information on the effects on soil microorganisms must be provided.

18 ECHA concludes that an appropriate study on Effects on soil microorganisms is needed.

2.3. Test selection and study specifications

19 Guidance on IRs and CSA, Section 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.

2.4. Outcome

20 On the basis of Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

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

3. Long-term toxicity to terrestrial plants

22 Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). 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.

As explained in the Request 1, the Substance is considered to be potentially very persistent and information on long-term toxicity on terrestrial plants must be provided.

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.

3.1. Information provided to fulfil the information requirement

23 Your registration dossier does not include any information on Long-term toxicity to terrestrial plants, instead you have adapted this information requirement referring to Annex IX, Section 9.4., column 2. To support the adaptation, you have provided the following justification: "As the test substance has a high potential to adsorb to the soil, the test substance belongs to Hazard category 3 as per Table R.7.11—2 in the ECHA guidance R.7c. In the absence of toxicity data under this category, the guidance recommends performing the risk assessment using modified EPM method (i.e., PEC × 10 / PNECscreen) and conducting one confirmatory long-term soil toxicity testing. While an Earthworm reproduction test has been planned with the test substance, the outcome of the chemical safety assessment indicates no risk for the soil compartment (PECx10/PNEC soil <1) suggesting no further requirement for testing for the terrestrial organisms."

3.1. Assessment of the information provided

3.1.1. The adaptation under Annex IX, Section 9.4., column 2 is rejected

24 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.7.11.6. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. 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.

25 Regarding the aquatic toxicity information used for the EPM, ECHA notes that Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates and fish referred to under Column 1, Section 9.1.5. and 9.1.6 respectively. Therefore, the information in your dossier does not allow to conclude on the aquatic toxicity of the Substance. Therefore, it is not possible to assign the Substance to any "Soil hazard category".

26 Therefore, the initial screening assessment using the EPM it is not applicable.

27 On this basis information on long-term toxicity on terrestrial plants must be provided.

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

3.2. Test selection and study specifications

29 The proposed Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

30 The OECD TG 208 (EU C.31.) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

3.3. Outcome

31 On the basis of Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

32 In your 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).
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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 1 July 2022.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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 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.

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, 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[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].

(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

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.

(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 and whether it is suitable for use by all members of the joint submission.

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

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:

- 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.

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