~~Confidential~~

Helsinki, 15 August 2022

Addressee
Registrant of JS_2EOBPADMA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
07/04/2022

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl) bismethacrylate and 2-{4-[2-(4-{2-[2-(methacryloyloxy)ethoxy]ethoxy}phenyl)propan-2-yl]phenoxy}ethyl methacrylate
EC number: 939-702-5

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 ***22 November 2023***.

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 testing on sediment organisms (Annex X, Section 9.5.1.; test method: EU C.35/OECD TG 225, in conjunction with Annex I, section 0.5)

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. 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 (Eisenia fetida/Eisenia andrei) (EU C.33/OECD TG 222) with the following justification: The Substance belongs to the soil hazard category 3 as "there are no indications that the substance is very toxic to aquatic organisms, and the substance is not readily biodegradable". Therefore, you have concluded that the approach is to evaluate the risk based on EPM and to conduct a confirmatory long-term soil toxicity study.

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

4 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 focussed 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.

5 The following information indicates that the 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 F study.

6 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 needs 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.

7 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.

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

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

1.2. Test selection and study specifications

10 The proposed Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei) (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

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

2. Effects on soil micro-organisms

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

2.1. Information provided to fulfil the information requirement

13 You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) with the following justification: "A study investigating effects on soil microorganisms is proposed, as it is a standard information requirement for Annex IX substances and this taxon is not covered by the Equilibrium Partitioning Method".

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

15 ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

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

2.2. Test selection and study specifications

17 The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (Guidance on IRs and CSA, Section R.7.11.3.1.).

2.3. Outcome

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

3. Long-term toxicity testing to sediment organisms

19 Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.). Nevertheless, according to Article 12(1) of and Annex VI to REACH, Annexes VI to XI stipulate minimum information requirements and, for each registration, the precise information requirements will differ under consideration of the Annexes as a whole and the overall requirements of registration, evaluation, and duty of care.

20 Annex VI, step 4 of the 'Guidance note on fulfilling the requirements of Annexes VI to XI' provides that the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than, or in addition to, the standard requirements. Furthermore, in accordance with Annex I, certain additional information may have to be generated if it is necessary for producing the chemical safety report (CSR). According to the last

subparagraph of Section 0.5. of Annex I of REACH, if the manufacturer or importer considers that further information is necessary for producing his CSR and that this information can only be obtained by performing tests in accordance with Annex IX and X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the CSR under the appropriate heading.

21 Guidance on IRs and CSA, Section R.7.8.10.3. on the 'rules according to the annexes to REACH and related considerations for toxicity to sediment organisms' specifies that substances with a high potential to adsorb onto sediment (e.g. log Kow >5 and/or Log Koc >3) require sediment assessment even at tonnages below 1000 t/y. In such case, further data generation is indicated if:

- the outcome of the screening assessment using the equilibrium partitioning method (EPM) results in a PEC/PNEC value above 1, or
- the EPM is not applicable, for instance if the substance is poorly water soluble and no effects are observed in aquatic studies.

22 The Substance is poorly water soluble (36.4 µg/L at 20.3°C, OECD 105) and no effects were observed in the available aquatic toxicity studies.

23 This information indicates that information on long-term toxicity to sediment organisms is needed.

3.1. Information provided to fulfil the information requirement

24 You have submitted a testing proposal for a Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225) with the following justification: "a long-term toxicity study on a sediment-dwelling organism is considered relevant as the EPM is not a viable method to derive sediment PNECs due to lack of significant effects in aquatic (pelagic) toxicity studies and as the substance is expected to be strongly adsorbing".

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

26 ECHA therefore agrees that an appropriate study on long-term toxicity to sediment organisms is needed.

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

3.2. Test selection and study specifications

28 The proposed Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225) is appropriate to cover the information requirement for long-term toxicity to sediment organisms (Guidance on IRs and CSA, Section R.7.8.9.1.).

3.3. Outcome

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

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 20 September 2021.

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 but amended the deadline.

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 15 months from the date of adoption of the decision. You justify the extension based on documentary evidence supporting the limited availability of the Contract Research Organisations (CROs) for perfoming the study under the request 1 (OECD TG 222).
>
> On this basis, ECHA has granted the request and extended the deadline to 15 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 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]

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

(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 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].

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

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.