~~Confidential~~

Helsinki, 25 October 2022

Addressees
Registrants of JS_42594-17-2 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
25/02/2021

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: (octahydro-4,7-methano-1H-indenediyl)bis(methylene) diacrylate
EC number: 255-901-3
CAS number: 42594-17-2

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 ***2 May 2025***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) by oral route, in rats;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in one species (rat or rabbit);

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)

5. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: OECD TG 222)

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

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information" required under Annex IX of REACH.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

[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 A: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-days)

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

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

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic 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.

ECHA received third party information concerning the testing proposal during the third party consultation.

A third party has noted that for so called "low toxicity substances" (substances which report a NOAEL of 1000 mg/kg bw/d), there is no added value for the human risk assessment if a 90-day study is performed: "*According to the Registration Dossier, a 28-day study (OECD 407) is available for the registered substance in which no adverse effects of treatment were reported at dose levels of up to and including the limit dose of 1000 mg/kg bw/d. Published analyses of toxicological data in REACH Registration Dossiers (Taylor et al, 2014; Taylor & Andrew, 2017) demonstrate that, for low toxicity substances reporting a NOAEL of 1000 mg/kg bw/d, there is no added value for the human risk assessment if a 90-day study is performed. As this substance appears to meet the definition of a 'low toxicity substance', a 90-day study is not scientifically justified and not in the interests of animal welfare*".

ECHA understands that the third party comments refer to the adaptation possibility under Annex IX, Section 8.6.2., column 2, first subparagraph, fourth indent. This adaptation specifies that a sub-chronic toxicity study (90-day) does not need to be conducted if "*the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day study, particularly if such a pattern is coupled with limited human exposure*". ECHA notes that all criteria need to be met.

ECHA observes that the third party comments addressed only the criterion concerning "no evidence of toxicity". The third party did not submit information regarding the other cumulative criteria under Annex IX, Section 8.6.2., column 2, first subparagraph, fourth indent.

Therefore, based on the information submitted by the third party the cumulative criteria listed in Annex IX, section 8.6.2., column 2, first subparagraph, fourth indent are not met. ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.6.2., column 2, first subparagraph, fourth indent.

Based on the above, ECHA therefore agrees that a 90-day study is necessary.

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

1.2 Specification of the study design

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.

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity (ECHA Guidance R.7a, Section R.7.5.4.3.2.).

1.3. Outcome

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. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD 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

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

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.

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

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

2.2 Specification of the study design

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.).

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

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 on aquatic invertebrates

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

3.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211).

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

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

3.2 Test selection and study specifications

The proposed *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 (ECHA Guidance R.7.8.4.1.).

3.3 Outcome

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

4. Long-term toxicity testing on fish

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

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

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.

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

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

4.2 Test selection and study specifications

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 (ECHA Guidance R.7.8.4.1.).

4.3 Outcome

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

5. Long-term toxicity testing on terrestrial invertebrates

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 (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

ECHA Guidance 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.

Under Section 5.2.1. of your technical dossier where you report 28.1% degradation after 28 days in OECD TG 301F and 24.5% degradation after 28 days in OECD TG 301D. Therefore, the Substance is concluded not to be readily biodegradable. Your technical dossier does not include any specific soil biodegradation data.

Therefore, the Substance is assumed to be highly persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

5.1 Information provided to fulfil the information requirement

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.4., Column 2. In support of your adaptation, you provided the following justification: "*Based on an integrated testing strategy (ITS), the test substance is assigned to soil hazard category 3…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.*"

We have assessed this information and identified the following issues:

A. Adaptation to omit the study under Annex IX, Section 9.4., Column 2.

As specified 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. The choice of the appropriate tests depends on the outcome of the chemical safety assessment.

In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity, which rely 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.

As already explained above, the Substance is concluded to be highly persistent in soil.

Furthermore, the information in your dossier is currently incomplete and therefore it is not possible to conclude on the toxicity of the Substance; see sections C.3 and C.4.of this Appendix.

The information from your dossier indicates that the Substance falls into the soil hazard category 3 (HC3) described in the ITS for soil toxicity. Hence, one confirmatory long-term toxicity test must be provided to confirm the outcome of the screening assessment.

B. Additional test on soil invertebrates is required under Article 40(3)(c) of REACH.

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 at Annex IX covers short-term toxicity on invertebrates (Section 9.4.1.) and on plants (Section 9.4.3.) and effects on soil micro-organisms (9.4.2.). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Under ECHA Guidance section R.7.11.5.3 long-term soil organism toxicity data should include an invertebrate, a higher plant study and a study on microorganisms.
As concluded above the Substance highly persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

In the comments to the draft decision, you considered that the request under Annex C.6 is sufficient to fulfil the confirmatory experimental information as described in ECHA Guidance ECHA Guidance R.7.11.6.3 for substances that falls into the soil hazard category 3 (HC3).

However, as specified in the Guidance on IRs and CSA, Table R.7.11-2, and ECHA Guidance R.7.11.5.3., the confirmatory test must be conducted with the most sensitive organism group (if any) as indicated from aquatic toxicity data. 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.

As already explained under in point "A." above, the information in your dossier is currently incomplete and therefore it is not possible to conclude on the toxicity of the Substance.

You have provided a testing proposal on effects on soil micro-organisms which is addressed under C.6. However, you have not provided a testing proposal for long term effects on soil invertebrates.

On this basis, ECHA concludes that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

5.2 Test selection and study specifications

The Earthworm Reproduction Test (test method: OECD TG 222), the Enchytraeid Reproduction Test (OECD TG 220) and the Collembolan Reproduction Test in Soil (OECD TG 232) are appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

5.3 Outcome

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. Therefore, you are requested to conduct an Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222, or Enchytraeid reproduction test OECD 220, or Collembolan reproduction test in soil OECD 232 with the Substance.

6. Effects on soil micro-organisms

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

The intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined in Annex IX, Section 9.4., Column 2, second paragraph does not apply for the information requirement on Effects on soil micro-organisms.

6.1 Information provided to fulfil the information requirement

You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216).
ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

In the comments to the draft decision, you agree to perform the requested study. You also requested clarification on the appropriateness of the Nitrogen Transformation Test (EU C.21/OECD TG 216) as confirmatory long-term toxicity test for a soil HC 3 substance. A clarification is provided in the reasons in section C.5.1 above.

Furthermore, under Article 40 of REACH, ECHA must examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. 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.

Your registration dossier does not include a study or an adaptation on the effects on microorganisms and therefore ECHA concluded that this information is needed.

6.2 Test selection and study specifications

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 (ECHA Guidance R.7.11.3.1.).

6.3 Outcome

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

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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].

B. 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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

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

Appendix C: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (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 synthetize its relevant constituents and/or fractions.

Appendix D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 February 2020.

ECHA held a third party consultation for the testing proposal(s) from 22 April 2021 until 7 June 2021. ECHA received information from third parties (see Appendix C.1.).

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 amended the deadline.

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to either 24 or 30 months from the date of adoption of the decision. You justify your request for extension on grounds of laboratory availability, for which you also provided a detailed study plan regarding the OECD TG 408 and OECD TG 414 studies.
>
> On this basis, 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.

ECHA received proposal(s) for amendment and modified the draft decision. The information initially required at Annex VII and VIII level was removed from the decision as proposed by a competent authority of a Member State, given that the respective information requirement(s) are not triggered at these Annex levels. Consequently, the initially concerned addressees at those Annex levels were also removed from the decision.

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

Your comments on the proposed amendment were taken into account by the Member State Committee.

In your comments, you agree that the Substance may not be considered as poorly water soluble although you state that this term has an unclear definition. You also agree that reference to OECD GD 23 may be removed from the decision.

Nevertheless, you note that it is very likely that the long-term aquatic toxicity studies proposed may need to be obtained by the initially concerned addressees at Annex VII and VIII levels for the purpose of a harmonised hazard assessment (e.g. PNEC values) among all registrants of the Substance. Therefore, you consider that no addressees should be removed from the addressee list of the decision.

Note that this decision is based on the information currently available in the registration dossier for the Substance. Therefore, as indicated above, the information initially required at Annex VII and VIII levels as well as the initially concerned addressees at those Annex levels cannot be part of this decision as this information is not triggered at these Annex levels based on information that is currently available.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-78 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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.

Appendix E: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[7]

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.