~~Confidential~~

Helsinki, 08 March 2022

Addressees
Registrants of Reconsile EC#221-336-6 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
08/07/2021

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: N-[3-(dimethoxymethylsilyl)propyl]ethylenediamine
EC number: 221-336-6

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 ***13 June 2023***.

A. Information required from 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: OECD TG 222) on the hydrolysis product N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2)

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216) on the hydrolysis product N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2)

3. Long-term toxicity testing 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) on the hydrolysis product N-[3- (dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2)

The reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendix "Reasons to request information required under Annexes IX of REACH".

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".

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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

ECHA understands that you intend to fulfil the information required for

- Long-term toxicity testing on terrestrial invertebrates,
- Effects on soil micro-organisms, and
- Long-term toxicity to terrestrial plants

by way of adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific information required in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

You have provided some justification for the read-across in IUCLID Section 6.3. and Section 7.2. of your CSR.

You intend to read-across between the main hydrolysis product of the Substance, N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine, no EC No. (CAS RN 3069-29-2) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of the terrestrial toxicity to be based on testing the hydrolysis product: "*The substance hydrolyses rapidly to form N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine and methanol*". As supporting information you have provided a hydrolysis study with the registered substance ([redacted], 2006) that indicates fast hydrolysis to N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine and Methanol (EC 200-659-6). Specifically, you report hydrolysis half-lives of <3 minutes at pH 4, 15 minutes at pH 7 and <3 minutes at pH 9 at 20-25°C.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the rapid formation of a transformation product that corresponds to the selected source substance. The properties of your Substance are predicted to be quantitatively equal to those of the selected source substance.

ECHA agrees that the information you provided indicates that the Substance hydrolyses fast to form the selected source substance. Based on the available hydrolysis data, the Substance is expected to be unstable over the duration of terrestrial toxicity tests. With a half-life of 15 minutes at pH 7, the loss of the parent substance is expected to be very fast and testing of the parent substance is unlikely to be technically feasible. In this context, ECHA Guidance

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

R.7.11.4.3 specifies that the terrestrial hazard assessment needs to consider the properties (including toxic effects) of degradation products that may be formed in soil. ECHA also notes that methanol would be formed but considering the high volatility of this substance it is not expected to remain in the soil compartment.

Conclusion on the read-across approach used to predict ecotoxicological properties

Considering the above, ECHA concludes that the read-across is plausible and that testing the main known hydrolysis product is acceptable.

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

This decision is based on the examination of the testing proposals you submitted.

1. 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.

Based on the information in your registration dossier the substance is considered as not readily bioavailable and there are no soil specific biodegradation data

Therefore, the Substance is considered potentially highly persistent in soil. On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222) with the following justification:

- No long-term terrestrial toxicity data are available for the Substance;
- You refer to ECHA Guidance on IR and CSA, Table R.7.11-2 which states that "*If PEC/PNECscreen >1 or indication of risk from confirmatory long-term soil toxicity test: Conduct long-term toxicity tests according to the standard information requirements Annex X (invertebrates and plants), choose lowest value for derivation of PNECsoil*". You indicate that "*The highest terrestrial RCR based on PEC x 10 / PNEC is 4.69 related to deposition from air*";
- You state that "*The substance hydrolyses rapidly to form N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine and methanol. No biodegradation is expected for the silanol hydrolysis product, N-[3-(dihydroxymethylsilyl)propyl] ethylenediamine*";
- You conclude that "*in accordance with the ECHA guidance, because the PEC/PNECscreen is >1 and the hydrolysis product is considered persistent in soil (DT50 >180 days), long-term terrestrial invertebrate and plant tests are proposed*".

You intend to test the following hydrolysis product of the Substance: N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine (CAS RN 3069-29-2 which corresponds to EC No. 221-336-6). ECHA understands that you intend to fulfil this information requirement through an adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

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

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

1.2. Grouping of substances and read-across approach

As stated in the Appendix on Reasons common to several requests, ECHA considers the read-across from the hydrolysis product N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine as plausible.

1.3. Test selection and study specifications

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

1.4. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2), as specified above.

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

2. Effects on soil micro-organisms

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

You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) with the following justification: "*Toxicity was observed in the aquatic microorganism test (IUCLID Section 6.1.7, CSR Section 7.4), read across from a structural analogue (16 hour EC50 67 mg/l; EC10 25 mg/l (*Pseudomonas putida*, growth rate) ([redacted], 1994)). ECHA guidance Chapter R.7c (ECHA 2017) states* "Where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC to be derived." *A soil microorganisms nitrogen inhibition test (OECD 216) is therefore proposed"*.

You intend to test the following hydrolysis product of the Substance: N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine (CAS RN 3069-29-2 which corresponds to EC No. 221-336-6). ECHA understands that you intend to fulfil this information requirement through an adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

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

ECHA agrees that an appropriate study on Soil Micro-organisms is needed.

2.2. Grouping of substances and read-across approach

As stated in the Appendix on Reasons common to several requests, ECHA considers the read-across from the hydrolysis product N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine as plausible.

2.3. Test selection and study specifications

ECHA Guidance 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

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2), as specified above.

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

3. Long-term toxicity to terrestrial plants

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

As stated in Appendix A.1.the Substance is considered potentially highly persistent in soil. On this basis information on long-term toxicity on terrestrial plants must be provided.

3.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a long term Terrestrial Plant Test (test method: OECD TG 208). ECHA understands that the justification provided in Appendix A.1. equally applies to your testing proposal on long-term toxicity to plants. You state that "*a tiered testing approach is proposed with the OECD 222 test to be conducted first in order to establish that stability and homogeneity is feasible for the earthworm test prior to conducting the OECD 208 plant test*".

You intend to test the following hydrolysis product of the Substance: N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine (CAS RN 3069-29-2 which corresponds to EC No. 221-336-6). ECHA understands that you intend to fulfil this information requirement through an adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

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

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

3.2. Grouping of substances and read-across approach

As stated in the Appendix on Reasons common to several requests, ECHA considers the read-across from the hydrolysis product N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine as plausible.

3.3. Test selection and study specifications

The proposed Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 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.

3.4. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with N-[3-(dihydroxymethylsilyl)propyl]ethylenediamine with EC No. 221-336-6 (CAS RN 3069-29-2), as specified above.

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

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[4].

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. As stated under Appendix on Reasons common to several requests ECHA considers testing with the hydrolysis product (N-[3- (dihydroxymethylsilyl) propyl]ethylenediamine) with EC No. 221-336-6 (CAS RN 3069-29-2) for the purpose of assessing terrestrial toxicity as plausible.

2. Information on the Test material needed in the updated dossier
    - You must report the identity, the composition and the impurities 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[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 14 August 2020.

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 amended the deadline

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 18 months from the date of adoption of the decision. You provided documentary evidence for your request for extension of the deadline covering both tiered and parallel testing approaches. Based on the information provided the studies can be completed within 10 months.
>
> On this basis, ECHA has extended the deadline to 12 months.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix D: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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.

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

OECD Guidance documents[9]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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.

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

Appendix E: 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]
[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.