~~Confidential~~

Helsinki, 12 August 2022

Addressees
Registrant(s) of RECONSILE EC# 404-370-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
31 August 2021

Registered substance subject to this decision ("the Substance")
Substance name: Dicyclopentyldimethoxysilane
EC number: 404-370-8

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 ***19 May 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 aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

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

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

5. 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 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 aquatic invertebrates

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

1.1. Information provided to fulfil the information requirement

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

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

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

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

1.2. Test selection and study specifications

6 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 (Guidance on IRs and CSA, Section R.7.8.4.1.).

7 The Substance is difficult to test due to rapid hydrolysis of 19 hours at pH 7 and 25°C (OECD 111, 2012). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

1.3. Outcome

8 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. Long-term toxicity testing on fish

9 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

2.1. Information provided to fulfil the information requirement

10 You have adapted this information requirement by referring to Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following statement: "In accordance with Column 2 of REACH Annex IX, the long-term aquatic toxicity to fish study does not need to be conducted as the chemical safety assessment according to Annex I indicates that this is not necessary".

2.2. Assessment of the information provided

11 We have assessed this information and identified the following issue:

2.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

12 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

13 Your adaptation is therefore rejected.

14 Therefore, the information requirement is not fulfilled.

15 In the comments to the draft decision, you note your intention to adapt this information requirement based on Annex XI, Section 3.2(a). The information in your comments is not sufficient for ECHA to make an assessment because you have only provided an intention to adapt this information requirement without supporting information. You remain responsible for complying with this decision by the set deadline.

2.3. Test selection and study specifications

16 The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (Guidance on IRs and CSA, Section R.7.8.4.1.).

17 OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under Request 1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Request 1.

2.4. Outcome

18 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. As explained above, the information requirement for long-term toxicity on fish is not fulfilled. Therefore, under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

3. Long-term toxicity testing on terrestrial invertebrates

19 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.

20 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.

21 Based on the information from your registration dossier the Substance is potentially very persistent. Under Section 5.2.1. of your technical dossier you report 12% degradation after 28 days based on OECD TG 301C. Your technical dossier currently does not include any specific simulation data for biodegradation in soil.

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

3.1. Information provided to fulfil the information requirement

23 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 is categorised as soil Hazard Category 3 due to persistence and aquatic toxicity >1 mg/l. According to ECHA guidance, a confirmatory long-term terrestrial test should be conducted for Hazard Category 3 substances."

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

25 With a view to your justification, ECHA observes that the information in your dossier does not allow conclusions on the aquatic toxicity of the Substance (see the reasons for requests 1 and 2 in this decision). Therefore a screening assessment using the equilibrium partitioning method cannot be conducted and the tests as set out under Annex IX, Section 9.4. need to be provided.

26 In any case, your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.

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

28 In the comments to the draft decision, you note your intention to adapt this information requirement based on the integrated testing strategy (ITS) for Effects on Terrestrial Organisms, Guidance on IRs and CSA, Section R.7.11.16.. The information in your comments is not sufficient for ECHA to make an assessment because you have only provided an intention to adapt this information requirement without supporting information. You remain responsible for complying with this decision by the set deadline.

3.2. Test selection and study specifications

29 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).

3.3. Outcome

30 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. Effects on soil micro-organisms

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

4.1. Information provided to fulfil the information requirement

32 You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216).

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

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

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

4.2. Test selection and study specifications

36 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.).

4.3. Outcome

37 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 to terrestrial plants

38 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.

39 As explained in the above reasons for request 3, the Substance is concluded to be potentially very persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

5.1. Information provided to fulfil the information requirement

40 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided following justification: "an earthworm reproduction test and a soil microorganisms test are proposed. Algae were the least sensitive trophic level, therefore further testing with terrestrial plants is not required."

41 ECHA assessed this information and identified the following issue:

42 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.

43 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.

44 As explained in the above reasons for requests 1 and 2, the information in your dossier is currently incomplete and therefore it is not possible to conclude on the aquatic toxicity of the Substance. Therefore assignment of the Substance to any "soil hazard category" is not possible.

45 Therefore, an initial screening assessment using the EPM cannot be conducted and the tests as set out under Annex IX, Section 9.4. need to be provided.

46 ECHA concludes that an appropriate long-term toxicity study on terrestrial plants is needed.

47 In the comments to the draft decision, you note your intention to adapt this information requirement based on the integrated testing strategy (ITS) for Effects on Terrestrial Organisms, Guidance on IRs and CSA, Section R.7.11.16.. The information in your comments is not sufficient for ECHA to make an assessment because you have only provided an intention to adapt this information requirement without supporting information. You remain responsible for complying with this decision by the set deadline.

5.2. Test selection and study specifications

48 The Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity to plants (Guidance on IRs and CSA, Section R.7.11.3.1.).

49 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.

5.3. Outcome

50 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 the Effects on terrestrial organisms at Annex IX covers short-term toxicity on invertebrates (Section 9.4.1.), effects on soil micro- organisms (Section 9.4.2.), short-term toxicity on plants (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. However, you have provided testing proposals for long-term testing on invertebrates and on the effects on soil micro- organisms only. Therefore, under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

51 ECHA notes that the deadline set in this decision allows for sequential testing. You may wait for the results from the requests 1 and 2 and, depending on these results, conduct this study. The results from the information requests 1 and 2 may also allow performance of an initial screening assessment using the EPM as set out under Annex IX, Section 9.4.

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 14 October 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 21 to 30 months from the date of adoption of the decision. You justify the extension based on documentary evidence provided on the availability of the Contract Research Organisations (CROs).
>
> On this basis, ECHA has granted the request and extended the deadline to 30 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.

> The deadline of the decision has been exceptionally extended by additional 3 months from the deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

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.

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