

Helsinki, 28 October 2021

Addressees

Registrants of JS_SDA_Product listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision

04/12/2019

Registered substance subject to this decision, hereafter 'the Substance'

Substance name: Product of Semi-Dry Absorption method of Flue Gas Desulphurization (SDA Product)

List number: 931-259-6

CAS number: NS

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 November 2022**.

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. Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: EU C.8./OECD TG 207)
2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216 and test method: EU C.22./ OECD TG 217)
3. Short-term toxicity on terrestrial plants (Annex IX, Section 9.4.3; test method: EU C.31./OECD TG 208, with at least three species)

Reasons for the request(s) are explained in the following Appendix entitled "Reasons to request information required under Annexes 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 to X to REACH, for registration at more than 1000 tpa.

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 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>.

Approved¹ under the authority of Christel Schilliger-Musset, 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

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

1. Short-term toxicity to terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm acute toxicity test (test method: EU.C.8/OECD TG 207).

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

ECHA agrees that an appropriate study on short-term toxicity terrestrial to invertebrate is needed.

1.2. Test selection and study specifications

The proposed earthworm acute toxicity test (test method: EU.C.8/OECD TG 207) is appropriate to cover the information requirement for short-term toxicity to invertebrates (ECHA Guidance R.7.11.3.1.).

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.

In your comments on the draft decision, you specify that you do not agree with the proposed tests. You specify that you "*continuously do ecotests EN ISO 7346-2; EN ISO 11348-1,2; EN ISO 6341*" and that the results show "*no impact on the environment*". Finally, you state that "*the production of SDA is decreasing every year [...] [and that you] will also stop producing SDA by 2027*".

ECHA notes that, in accordance with Articles 10(a) and 12(1) of REACH, you must provide the information specified in Annexes VII to X to REACH for registration at more than 1000 tpa. ECHA notes that you have neither provided information for this endpoint nor an adaptation under the specific rules for adaptation of Annex IX, Section 9.4., column 2 or the general rules for adaptation specified under Annex XI to REACH. Therefore, ECHA maintains that an appropriate study is needed.

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).

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

ECHA agrees that appropriate information on long-term adverse effects on soil microorganisms is needed.

2.2. Test selection and study specifications

ECHA Guidance R.7.11.3.1. specifies that the 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. However, as specified in OECD TG 216 and 217, if agrochemicals (e.g. crop protection products, fertilisers, forestry chemicals) are tested, both the carbon transformation and the nitrogen transformation tests must be conducted. Your report that the substance is used as co-formulant in plant protection products. Therefore, information on both carbon transformation and nitrogen transformation must be provided.

Under Section 3.5. of your dossier, you report that the substances in used in fertilisers. Therefore, both the Soil Microorganisms: Carbon Transformation Test (EU C.22/OECD TG 217) and Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) need to be conducted.

2.3. Outcome

Under Article 40(3)(b) your testing proposal is accepted under modified conditions and you are requested to conduct the test with the Substance, as specified above.

You did not provide specific comments for this endpoint. The reply to your comment under Appendix A.1 also applies to this information requirement.

3. Short-term toxicity on terrestrial plants

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

3.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test (test method: OECD TG 208).

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

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

3.2. Test selection and study specifications

The proposed Plant Test: Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) is appropriate to cover the information requirement for short-term toxicity on terrestrial plants (ECHA Guidance R.7.11.3.1.).

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.

You did not provide specific comments for this endpoint. The reply to your comment under Appendix A.1 also applies to this information requirement.

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 summaries².

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,
 - The reported composition must include all constituents of each Test material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

² <https://echa.europa.eu/practical-guides>

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers³.

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 ecotoxicity 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.

Appendix D: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 17 February 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.

ECHA took into account your comments and did not amend the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH

Appendix E: List of references - ECHA Guidance⁴ and other supporting documentsEvaluation 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 documents⁷

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.

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

