

Helsinki, 20 October 2020

Addressees

Registrants of JS_701-326-2 listed in the last Appendix of this decision

Date of submission for the dossier subject of a decision

23/03/2020

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

Substance name: Reaction mass of (3aR,5aS,9aS,9bR)-3a,6,6,9a-tetramethyldodecahydronaphtho[2,1-b]furan and (3aS,5aR,9aR,9bS)-3a,6,6,9a-tetramethyldodecahydronaphtho[2,1-b]furan

EC number: 701-326-2

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 A TESTING PROPOSAL**

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of **25 January 2022**.

A. Requirement applicable to all the Registrants subject to Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1. and Annex I, Section 0.5; test method EU C.20./OECD TG 211) with the Substance;

B. Requirements applicable to 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) with the Substance;
2. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222), with the Substance.

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa.

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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 for the requirements applicable to all the Registrants subject to Annex VII of REACH

This decision is based on the examination of the testing proposal you submitted

1. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.5.)

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). According to Annex VII, Section 9.1.1., the registrant may consider long-term toxicity testing on aquatic invertebrates instead of a short-term study.

You have provided an OECD TG 202 study short-term toxicity study on aquatic invertebrates and a QSAR prediction of long-term toxicity on aquatic invertebrates for the Substance.

According to section 0.5 of Annex I of REACH:

"If the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex IX or X, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the chemical safety report under the appropriate heading."

You have submitted a testing proposal for the Daphnia magna reproduction test (OECD TG 211) and indicated *"An experimentally- determined EC10 value would allow to conclude appropriately on the environmental classification of the registered substance."*

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex VII, Section 9.1.1 of the REACH Regulation and can provide relevant information for the chemical safety report.

Therefore, under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Study design

The Substance is difficult to test due to the low water solubility. OECD TG 210 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 210. 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 solution.

Appendix B: Reasons for the requirements applicable to all the Registrants subject to Annex IX of REACH

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

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

You have provided a QSAR prediction of long-term toxicity on aquatic invertebrates for the Substance.

You have submitted a testing proposal for the Daphnia magna reproduction test (OECD TG 211) and indicated "*An experimentally- determined EC10 value would allow to conclude appropriately on the environmental classification of the registered substance.*"

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation and can provide relevant information for the chemical safety report.

Therefore, under Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test.

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.1.

2. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Short-term toxicity testing on terrestrial invertebrates is a standard information requirement at Annex IX of REACH Section 9.4.1. However, if the Substance has a high potential to adsorb to soil or is very persistent, the registrant shall consider long-term toxicity testing instead of short-term (Annex IX, Section 9.4.1, column 2).

The current registration dossier does not contain any information on toxicity to terrestrial organisms. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for long-term toxicity testing on earthworms according to OECD TG 222 (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)) with the Substance with a limit test as a first step.

The Substance is considered having a high potential to adsorb to soil thus, a long-term test on terrestrial invertebrates should be considered. In addition, the Substance meets the requirements to be classified in "Soil Hazard Category 3" (ECHA guidance R.7.c 2017). Therefore, under Article 40(3)(a) of REACH, you are requested to carry out the proposed test with the Substance.

Appendix C: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 5 September 2019.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The decision making followed the procedure of Articles 50 and 51 of REACH, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

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

The timeline indicated in the draft decision to provide the information requested was 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to at least September 2021. You justified your request stating that the 9-month deadline was not achievable due the impact of the current situation on the availability of testing laboratories. You also provided a communication from a testing laboratory confirming that the studies could be only reported in September 2021. You further requested that if possible the deadline should be aligned with the timeline indicated in the compliance check decision notified to you on the same Substance, as this would enable a single dossier update to provide both sets of information.

ECHA acknowledges the information submitted. However, new information on the properties of the substance should be included in the registration without unnecessary delay.

Therefore, ECHA has only partially granted the request and set 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 adopted the decision under Article 51(3) of REACH.

Appendix D: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.
2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State(s).

3. Test guidelines, GLP requirements and reporting

Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

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.

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: 'How to report robust study summaries'².

4. Test material

Selection of the test material(s)

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

Technical reporting of the test material

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"³.

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

³ <https://echa.europa.eu/manuals>

5. List of references of the ECHA Guidance and other guidance/ reference documents⁴

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 in this decision.

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

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.

OECD Guidance documents

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

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

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>

Appendix E: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.