

Helsinki, 10 February 2020

Addressees

Registrants of [REDACTED] listed in the last Appendix of this decision

Date of submission for the submitted dossier subject of a decision

06/09/2018

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

Substance name: 1-Dodecene, dimers

EC number: 814-509-8

CAS number: 62132-67-6

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 **17 February 2021**.

A. Requirement applicable to the Registrants subject to Annex IX of REACH

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance.

Conditions to comply with the request

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII to IX of REACH, if you have registered a substance at 100-1000 tpa.

The testing material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in Appendix entitled Observations and technical guidance.

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, where relevant.

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 requirement applicable to the Registrant subject to Annex IX of REACH

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

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX, Section 8.7.2. to REACH.

You have submitted a testing proposal for a PNDT study according to OECD TG 414.

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.

You proposed testing with the rat as a first species and by the oral route. ECHA agrees with your proposal. The rat or rabbit is the preferred species under the OECD TG 414³. The oral route is the most appropriate route of administration to investigate reproductive toxicity².

In your comments to the draft decision you confirmed your *"intention to commission initially a dose - range finding study in the rat on this substance and subsequently the OECD 414 (PNDT) study in the rat, by the oral route"*.

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

In addition, in your comments to the draft decision you state your intentions to use the proposed test as part of your Poly-Alpha Olefins category testing strategy.

² ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix B: Procedural history

ECHA received your registration containing the testing proposal for examination on 6 September 2018.

ECHA held a third party consultation for the testing proposal from 2 November 2018 until 17 December 2018. ECHA did not receive information from third parties.

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 the REACH.

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

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 request.

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 C: 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 request in this decision, or to otherwise fulfil the information requirement 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

According to 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.

According to Article 13(4) of REACH ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

According to 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'³.

4. Test material for UVCB substances – Selection and Technical Reporting

While selecting the test material you must take into account 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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that *"if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible..."*.

In order to meet this requirement, all the constituents of the test material used for each test shall be identified as far as possible. For each constituent the concentration value in the test material shall be reported in the Test material section of the endpoint study record.

For this specific test material it is required as far as possible to provide analytical evidence that i) all constituents present are isomers of the molecular formula C₂₄H₄₈ and ii) cyclic, aromatic and quaternary structures are excluded as specified in the reported composition for the Substance. As the test material is of UVCB type, it is expected that its composition cannot be completely determined. To compensate for this fact, the manufacturing process for the test material shall be specified in the respective endpoint study record, under the Test material section. The description shall contain

³ <https://echa.europa.eu/practical-guides>

identification and composition of the starting material(s) used and all relevant process parameters that affect the composition. If the starting material(s) composition cannot be determined, this could be in turn compensated by specifying the manufacturing process of the starting material(s) (i.e. especially the starting material used to manufacture 1-dodecene). The information provided for the test material needs to be in line with the substance identity information reported for the Substance. Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf).

5. List of references of the ECHA Guidance 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

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.

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 D: The registrant to which the decision is addressed and the corresponding information requirement applicable to him

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