

Helsinki, 12 December 2019

Addressees

Registrants of PM_130_JS_DINCD listed in the last Appendix of this decision

Date of submission for the dossier subject of a decision

21/08/2018

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

Substance name: 1,4-Cyclohexanedicarboxylic acid, 1,4-diisononyl ester

EC number: 701-012-5

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 **20 December 2021**.

A. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats; with the Substance
2. 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 requested information

You have registered a substance at 100-1000 tpa, therefore you have to comply with the requirements of Annexes VII to IX of REACH.

Appendix A states the reasons for the requests for information to fulfil the requirements set out in Annex IX of REACH.

The test material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in Appendix C 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.

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 Schillinger-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 IX of REACH

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.);

A sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX, Section 8.6.2. to REACH.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) under the OECD TG 408.

You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees with your proposed testing in rats and by the oral route. The rat is the preferred species under the OECD TG 408. The most appropriate route of administration is the oral route² since the Substance is a liquid of very low vapour pressure and no uses with spray application that could potentially lead to aerosols of inhalable size, are reported.

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

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

A pre-natal developmental toxicity (PNDT) study for a first species is a standard information requirement in Annex IX, Section 8.7.2. to REACH.

You have submitted a testing proposal for a PNDT study under the OECD TG 414.

You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement 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 414. The oral route is the most appropriate route of administration to investigate reproductive toxicity³.

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

² ECHA Guidance R.7a, Section R.7.5.4.3

³ ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix B: Procedural history

ECHA received your registration containing the testing proposals for examination on 24 August 2018.

ECHA held a third party consultation for the testing proposals from 10 December 2018 until 24 January 2019. 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 within 30 days of the notification.

ECHA did not receive any comments within the 30 days.

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 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, 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'⁴.

4. Test material

Selection of the test material(s) for UVCB substances

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 in 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 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 constituent that has a 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. 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, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents".

⁴ <https://echa.europa.eu/practical-guides>

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.

Technical reporting of the test material for UVCB substances

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 value. 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" on the ECHA website (https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf).

5. List of references of ECHA Guidance documents⁵ relevant for information requirements

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.

⁵ <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

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

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