EUROPEAN CHEMICALS AGENCY

Helsinki, 26 May 2020

Addressees
Registrants of Dicyclopentadiene (LOA) listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
14/05/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 3a,4,7,7a-tetrahydro-4,7-methanoindene
EC number: 201-052-9
CAS number: 77-73-6

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 ***31 August 2022***.

A. Requirements applicable to all the Registrants subject to Annex X of REACH[1]

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rat or rabbit), oral route by gavage 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 Annexes VII to X of REACH, if you have registered a substance at above 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 test material used to perform the required studies shall be selected and reported in accordance with the specifications prescribed in Appendix 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.

Authorised[1] 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 all the Registrants subject to Annex X of REACH

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

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2., column 2) in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X 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 the Substance with the rabbit as a second species and by the oral route. ECHA agrees with your proposal. The rat or rabbit is the preferred species under the OECD TG 414. Testing should be performed with the rabbit or the rat as a second species, depending on the species tested in the first pre-natal developmental toxicity study. The oral route is the most appropriate route of administration to investigate reproductive toxicity[2]. In the provided combined repeated dose and reproductive/ developmental toxicity screening test in rats via oral route (1993), you reported lower viability index and birth weight in the offspring at 100 mg/kg bw/day. These effects are of concern and need to be followed up in a definitive pre-natal developmental toxicity study. Therefore the study should be performed by oral gavage, as this was the method of oral dosing in the Combined repeated dose and reproductive/developmental toxicity screening test in rats (1993) which showed developmental effects, and it is necessary to use the same dosing method (i.e. oral gavage) in order to investigate any developmental effects. An additional reason for the use of oral gavage is the potential for volatilisation either of the principal constituent, dicyclopentadiene, or of any impurities that may be toxicologically important. For these reasons, the homogeneity and stability of the test chemical under the conditions of administration (paragraph 39 of OECD TG 414) must be reported in the respective endpoint study record, under the Test material section.

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

In your comments to the draft decision, you indicated your agreement to perform the requested study. You also considered that the first species PNDT study (a request notified to you in a separate decision on a compliance check) should be conducted in rabbit before the initiation of the request in the present decision. You stated that if the results from the first species PNDT study in the rabbit indicate that classification of the Substance as reproductive toxicant in Category 1 is warranted, you will classify the Substance accordingly and apply the adaptation to waive the requested study in the present decision.

ECHA indeed notes that before performing a PNDT study in a second species you should consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species or any other new information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement and underlying scientific justification.

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

You provided comments on the Proposal for Amendment (PfA) submitted by one of the Member States Competent Authorities (MSCAs), regarding Appendix C.5, referring to characterisation of the Test Material. Firstly, you propose that the substances mentioned in the PfA are not present in the Substance and you are unaware of any registration "*with these substances in any significant portion*". Secondly, you indicate a wish to test a purified substance with high purity DCPD, and that this would be the most representative test material.

In respect of the first issue, we note that there is no need to test where you have a robust basis to exclude the presence of a constituent/impurity. ECHA notes that impurities, such as 2-methylbut-2-ene (EC no. 208-156-3), 4-vinylcyclohexene (EC no. 202-848-9), toluene (EC no. 203-625-9) and benzene (EC no. 200-753-7; CAS no. 9072-35-9), are listed in individual dossiers. Thus, when selecting the test material you will need to take into account this fact. In respect of the second issue, we agree that it may be a viable strategy to test the more highly purified DCPD. However, ECHA notes that the registration allows for non-DCPD constituents/impurities up to 20%, and it would be incumbent on you to identify what these non-DCPD constituents/impurities are, and to justify how these non-DCPD constituents/ impurities affect the properties of the Substance.

ECHA has therefore, amended point 5 of the Appendix C to reflect that the PfA concerns the technical reporting of the test material.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 15 May 2018.

ECHA held a third party consultation for the testing proposal from 28 February 2019 until 15 April 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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request.
ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s) and referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-69 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix C: Observations and technical guidance

1. The Substance subject to the present decision is listed in the Community rolling action plan (CoRAP).

2. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

3. 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).

4. 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 shall 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[3]'

5. 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.

   There is the potential for the test material to include impurities which have carcinogenic, mutagenic or reprotoxic properties, such as (but not limited to) 2-methylbut-2-ene (EC:

[3] https://echa.europa.eu/practical-guides

208-156-3), toluene (EC: 203-625-9), mixed xylenes (EC: 292-694-9 and EC: 215-535-7), 4-vinylcyclohexene (EC: 202-848-9) and n-hexane (EC: 203-777-6). To the extent technically feasible, the presence and concentration values of such CMR constituents must be determined empirically in the test material, reported, and the relevance for the Substance, as a whole, justified.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/manuals).

6. List of references of the ECHA Guidance documents[4]

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: 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]