

Helsinki, 5 September 2022

**Addressees**

Registrants of JS\_Dihydromyrcenol as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**

28/05/2021

**Registered substance subject to this decision ("the Substance")**

Substance name: 2,6-dimethyloct-7-en-2-ol

EC number: 242-362-4

**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 **10 June 2025**.

Requested information must be generated using the Substance unless otherwise specified.

**Information required from all the Registrants subject to Annex X of REACH**

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit).

The reasons for the decision(s) are explained in Appendix 1.

**Information required depends on your tonnage band**

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

**Appeal**

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of

Appeal of ECHA within three months of its notification to you. Please refer to <http://echa.europa.eu/regulations/appeals> for further information.

**Failure to comply**

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised<sup>1</sup> under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision

Appendix 2: Procedure

Appendix 3: Addressees of the decision and their individual information requirements

Appendix 4: Conducting and reporting new tests under REACH

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<sup>1</sup> 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 1: Reasons for the decision**

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**Reasons for the decision(s) related to the information under Annex X of REACH****1. Pre-natal developmental toxicity study**

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

*1.1 Submitted Testing proposal*

2 You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the Substance.

3 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. 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.

4 ECHA agrees that a PNDT study in a second species is necessary.

*1.2 Assessment of information provided in the dossier and in your comments on the draft decision*

5 In your comments on the draft decision, you suggest a temporary withdrawal of the testing proposal, as the results of an ongoing extended one-generation reproductive toxicity (EOGRT) study may warrant classification and adaptation of the information on this basis, or if additional parameters would be triggered for the second developmental toxicity study. Furthermore, the first species developmental toxicity study did not show relevant adversity and there is currently no concern for developmental toxicity to trigger further testing. You state that the PNDT study in a second species is purely justified on legal reasons by ECHA.

6 Firstly, ECHA notes that a PNDT study in a second species is indeed a legal requirement at Annex X (as indicated above). The requirements set out in Column 1 of REACH Annexes VII-X are cumulative, and therefore, under Annex X, Section 8.7.2. to REACH, a PNDT study on a species other than the species used for a PNDT study under Annex IX is required. It is in combination with the first species study results, namely NOAEL setting, that allows proper hazard identification for developmental toxicity.

7 Secondly, a valid column 2 adaptation for PNDT study in second species at Annex X would be classification for reproductive toxicity 1B for developmental toxicity, which is not given. It is possible that the EOGRTS contributes to such a classification but in the current situation the scenario is only hypothetical. Regarding your reference to additional parameters in the second PNDT study, ECHA further notes that its study design is standard and the results of the EOGRTS should have no impact on the parameters included in this study.

8 Furthermore, in the dossier you provided an adaptation according to Annex XI to REACH and statement: "*The substance is of low toxicological activity and no developmental effects were detected in any of the available studies on reproductive toxicity.*"

9 While you have not specified the Annex XI adaptation, ECHA understands that you refer to Annex X, Section 8.7., Column 2, third indent, under which the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, namely:

i. that there is no evidence of toxicity seen in any of the tests available, and

ii.that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure, and

iii.that there is no or no significant human exposure.

10 You justified the adaptation by stating that the Substance is of low toxicological activity and no developmental effects were identified. However, based on the data provided in your technical dossier, the physicochemical characteristics of the Substance makes absorption via oral and dermal routes likely and there are widespread uses by professionals (end-use washing and cleaning, end-use polishes and wax blends) and consumers (eg. end-use of washing and cleaning, air care products, polishes and wax blends).

11 Therefore, you have not demonstrated fulfilment of the three concomitant criteria provided above.

12 Thus, your adaptation is rejected and the information requirement is not fulfilled.

13 Based on the above, ECHA therefore considers that the testing proposal for the PNDD study in a second species can be further processed.

### *1.3 Specification of the study design*

14 You proposed testing in the rabbit as a second species. The study in the first species was conducted in the rat. The rat or the rabbit are the preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.). Therefore, the study must be conducted in the rabbit.

15 You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

### *1.4 Outcome*

16 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

## References

The following documents may have been cited in the decision.

### **Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)**

- Chapter R.4 Evaluation of available information; ECHA (2011).
- Chapter R.6 QSARs, read-across and grouping; ECHA (2008).  
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
- Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).  
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
- Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).  
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
- Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).  
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).  
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
- Chapter R.11 PBT/vPvB assessment; ECHA (2017).
- Chapter R.16 Environmental exposure assessment; ECHA (2016).

### **Guidance on data-sharing; ECHA (2017).**

All Guidance on REACH is available online: <https://echa.europa.eu/guidance-documents/guidance-on-reach>

### **Read-across assessment framework (RAAF)**

- RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
- RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:

<https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

### **OECD Guidance documents (OECD GDs)**

- OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
- OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
- OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
- OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

## **Appendix 2: Procedure**

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 12 July 2021.

ECHA held a third party consultation for the testing proposal(s) from 26 August 2021 until 11 October 2021. ECHA did not receive information from third parties.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

**Appendix 3: Addressees of this decision and their corresponding information requirements**

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

<b>Registrant Name</b>	<b>Registration number</b>	<b>Highest REACH Annex applicable to you</b>
[REDACTED]	[REDACTED]	[REDACTED]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

## Appendix 4: Conducting and reporting new tests for REACH purposes

### 1. Requirements when conducting and reporting new tests for REACH purposes

#### 1.1. 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 summaries<sup>2</sup>.
- (4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

#### 1.2. 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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers<sup>3</sup>.

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

<sup>3</sup> <https://echa.europa.eu/manuals>