EUROPEAN CHEMICALS AGENCY

Helsinki, 24 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465858-29-01/F
Substance name: (E)-7,11-dimethyl-3-methylenedodeca-1,6,10-triene
EC number: 242-582-0
CAS number: 18794-84-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 21/02/2019
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats using the registered substance. It is at the Registrant's discretion to perform the intended additional examinations during the testing program.**

You have to submit the requested information in an updated registration dossier by **2 November 2020**. You also have to update the chemical safety report, where relevant.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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] by Wim De Coen, Head of Unit, 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 1: Reasons

The decision of ECHA is based on the examination of the testing proposal submitted by you and scientific information submitted by third parties.

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

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that 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.

ECHA received third party information concerning the testing proposal during the third party consultation and acknowledges it.

A third party has in particular indicated the following: "*The registration dossier contains studies of 90-day oral toxicity in the rat and mouse and 2-year oral toxicity studies in the rat and mouse with the structural analogue, myrcene (CAS 123-35-3). The studies are of good quality and appear to be adequate (through read-across) to address the data requirement for farnesene. The proposed 90-day oral toxicity with farnesene does not therefore appear to be required in order to meet the REACH data requirement. The testing proposal is therefore questioned.*"

ECHA notes that you considered a read-across approach to beta-myrcene (CAS# 125-35-3) in your considerations of alternatives. However, you indicate that due to differences in physical properties and in *in vitro* absorption, you assumed that any potential exposure to the registered substance would be orders of magnitude lower than that to the analogue substance, beta-myrcene (CAS# 125-35-3) and the use of myrcene data would be a too conservative read-across approach. Hence, ECHA considers that the read-across as proposed by the third party does not constitute relevant scientific information in the context of the examination of your testing proposal.

ECHA notes in the current registration dossier under IUCLID section 7.5.1. you have submitted also an adaptation to this standard information requirement by using read-across approach following Annex XI, Section 1.5. of the REACH Regulation. In IUCLID section 13 of the current registration dossier, there is a document entitled [redacted] where you outline a [redacted].

ECHA notes throughout this documentation, you indicate that the read-across approach would be too conservative for this endpoint, the repeated dose toxicity, that there is an information gap and therefore you have submitted this testing proposal for this endpoint, on the registered substance. Conseqently, for the examination of this testing proposal, ECHA has not evaluated the read-across from beta-myrcene to the registered substance.

You proposed testing by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration.

More specifically, the substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

You proposed testing in rats. According to the test method OECD TG 408, the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

You proposed to extend the sub-chronic toxicity study (90 day) by including additional examinations/parameters such as assessment of sperm (motility, morphology, number), oestrus cycle measurements, and male/female reproductive organ and tissue histopathology, with an emphasis focus on liver and kidney pathology.

ECHA notes, that it is at your discretion to perform the intended additional examinations during the testing program as long as those additional examination do not interfere with the examinations according to test method OECD TG 408, and use the results to ensure the safe use of the substance. However, please note that the proposed extension of this study will not fulfil the standard information requirement in the registration dossier for reproductive toxicity set out in Annex X, Section 8.7.3.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: OECD TG 408).

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 16 February 2018.

ECHA held a third party consultation for the testing proposals from 23 April 2018 until 7 June 2018. ECHA received information from third parties (see Appendix 1).

This decision does not take into account any updates after **14 December 2018**, 30 calendar days after the end of the commenting period.

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.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

   In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.