

**ECHA Draft Decision communicated pursuant to Article 51 of the REACH Regulation**

Decision number: TPE-D-2114340336-55-01/F

Helsinki, 14 July 2016

**DECISION ON TESTING PROPOSALS SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006****For 4-hydroxy-2,2,6,6-tetramethylpiperidinoxyl, EC No 218-760-9 (CAS No 2226-96-2), registration number: [REDACTED]****Addressee: [REDACTED]**

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

**I. Procedure**

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 4-hydroxy-2,2,6,6-tetramethylpiperidinoxyl, EC No 218-760-9 (CAS No 2226-96-2), submitted by [REDACTED] (Registrant).

- Developmental toxicity / teratogenicity study (OECD 414), on the rat, oral route.

This decision is based on the registration as submitted with submission number [REDACTED], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 25 July 2015.

This decision does not imply that the information provided by the Registrant in his 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.

ECHA received the registration dossier containing the above-mentioned testing proposals for further examination pursuant to Article 40(1) on 2 December 2014.

ECHA held a third party consultation for the testing proposals from 16 February 2015 until 2 April 2015. ECHA did not receive information from third parties.

On 11 May 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on the registration dossier as updated by submission number [REDACTED].

On 16 June 2015 ECHA received comments from the Registrant on the draft decision.

On 22 July 2015 the Registrant updated his registration by submission number [REDACTED]. The updated dossier removed the testing proposal for a 90 day repeated dose toxicity study (OECD 408), and the Registrant has classified the substance as STOT Rep. Exp. 2 based on the outcome of the existing 28 day repeated dose toxicity study.

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The ECHA Secretariat considered the Registrant's comments and update.

On the basis of this information, the information request (Section II) and the Statement of Reasons (Section III) was amended. In particular, the request for a 90 day repeated dose toxicity study has been removed from this decision, and accordingly the ECHA Secretariat did not consider further the Registrant's comments regarding the 90 day repeated dose toxicity study.

On 3 March 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

**II. Testing required****A. Tests required pursuant to Article 40(3)**

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

**B. Deadline for submitting the required information**

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **21 July 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

**III. Statement of reasons**

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

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Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant proposed testing with the rat as a first species. The Registrant proposed testing by the oral route. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

**B. Deadline for submitting the required information**

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained a 90 day repeated dose toxicity study (Annex IX, Section 8.6.2.). The Registrant's comments to the draft decision requested an extension of the original deadline to 60 months, in order to allow for sequential testing. As the 90 day study is not addressed in the present decision, the ECHA Secretariat considers that a reasonable time period for providing the required information in the form of an updated IUCLID dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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In relation to the proposed tests, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

**IV. Information on right to appeal**

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at <http://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised<sup>[1]</sup> by Ofelia Bercaru , Head of Unit, Evaluation, E3

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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.