Decision number: TPE-D-0000003944-67-04/F

Helsinki, 5 September 2014

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For octadec-1-ene, CAS No 112-88-9 (EC No 204-012-9), 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)(e) thereof for octadec-1-ene, CAS No 112-88-9 (EC No 204-012-9) referred to as "substance subject to the present decision" below, submitted by [redacted] (Registrant).

More specifically, the dossier encloses a document "*Higher Olefins Testing Proposal*", which contains a testing plan to "*provide information that will meet the higher tier testing requirements of REACH*" for a group of substances, including the substance subject to this decision. The testing plan is summarised as follows:

1. Sub-chronic repeated dose toxicity study (OECD Guideline 408, oral route), species not specified, on the substance subject to the present decision, octadec-1-ene (CAS number 112-88-9)
2. Prenatal developmental toxicity study (OECD Guideline 414), species and route of administration not specified, on the substance subject to the present decision, octadec-1-ene (CAS number 112-88-9)
3. Two-generation reproduction toxicity study (OECD Guideline 416), species and route of administration not specified, on the substance subject to the present decision, octadec-1-ene (CAS number 112-88-9). The substance is proposed to be replaced by tetradec-1-ene UVCB (CAS No. 1120-36-1) as test material, if no effects in the respective OECD 408 and 414 studies with the the substance subject to this decision are detected.

1. The present decision relates only to the examination of the testing proposals 1 and 2

The testing proposal 3, for fulfilling the information requirement for a reproductive toxicity study (Annex X, 8.7.3.) is addressed in a separate decision although all these were initially addressed together in the same draft decision.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band 1000 tonnes or more per year. This decision does not take into account any updates after 1 August 2013, the date upon which ECHA notified its

draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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.

On 23 September 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals on prenatal developmental toxicity and two-generation reproduction toxicity set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 31 May 2011 until 15 July 2011. ECHA did not receive information from third parties.

On 3 January 2012, ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 24 and 26 January 2012, ECHA received comments from the Registrant indicating a changed testing strategy proposing additional tests for sub-chronic toxicity (90-day). Subsequently, on 05 March 2012 ECHA received an update of the registration dossier including a testing proposal for sub-chronic repeated dose toxicity.

The examination of the testing proposals for sub-chronic toxicity (90-day) was initiated upon the date when receipt of the complete registration dossier was confirmed on 05 March 2012.

ECHA held a third party consultation for the testing proposal on sub-chronic toxicity (90-day) from 25 June 2012 until 09 August 2012. ECHA did receive information from third parties (see section III below).

On 23 of July 2012 ECHA received a further update of the registration dossier.

ECHA considered the Registrant's comments received and the information included in the updated dossier. On that occasion, ECHA noted that the draft decision initially sent to the Registrant did not address all the defects present in the testing strategy initially proposed by him. ECHA considered that the omitted issues were significant and must therefore be considered in the final decision to be sent to the Registrant. Nevertheless, ECHA was mindful to give useful effect to the right to comment on arguments omitted in the previous draft decision, in accordance with Article 50(1) of the Regulation. In order to allow the Registrant to comment on grounds that should have been initially notified to him, ECHA decided to notify him, for comment, a modified draft decision including the grounds omitted in the previous draft decision. ECHA has also taken this opportunity to include in its assessment a testing proposal on a new endpoint included by the Registrant in its testing strategy, following its update of the dossier.

On 10 September 2012, ECHA sent the modified draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 10 October 2012, ECHA received comments from the Registrant indicating a now substantially changed category and read-across approach requesting additional time to develop a full new testing plan. Subsequently, on 07 March 2013 ECHA received an update of the registration dossier including a new test plan.

ECHA considered the Registrant's comments received. On basis of the updated dossier, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 1 August 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproduction toxicity study (Annex X, 8.7.3), and one relating to the testing proposals for subchronic repeated dose toxicity and prenatal developmental toxicity

On 4 October 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments to the Registrant into account.

After discussion in the Member State Committee meeting on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision relating to the testing proposals for subchronic repeated dose toxicity and prenatal developmental toxicity as modified at the meeting was reached on 7 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

In parallel, following a compliance check on the identity of the substance "nonene (CAS No. 27215-95-8)", the multiple registrants of that substance jointly requested a change of the substance's identifiers to "nonene, branched (CAS No. 97280-95-0)", which reflects the substance actually manufactured and imported. After verifying that this modification had no consequence on the selection of that substance for the proposed testing strategy, ECHA has adapted the present decision *mutatis mutandis*.

II. Testing required

The Registrant shall carry out the following tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and substances:

1. Sub-chronic repeated dose toxicity study in rats, oral route (Annex IX, 8.6.2., test method: EU B. 26/OECD 408) on the the substance subject to this decision; and

2. Pre-natal developmental toxicity study in rat or rabbit, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414) on the the substance subject to this decision.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **12 September 2016** an update of the registration dossier containing the information required by this decision.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

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 and scientific information submitted by third parties.

1. Repeated dose toxicity study

a) Examination of the testing proposal

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

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.

The Registrant proposed testing by the oral route. In the light of the physicochemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B. 26/OECD 408, the rat is the preferred species. ECHA considers the default parameter appropriate and testing should be performed with the rat as species to be used.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information:

The third Party proposed ECHA to take into account a weight-of-evidence approach for before further tests on vertebrate animals are required. As part of this approach, the third party referred to existing data from repeated dose toxicity studies in rodents with substances others than the one registered. ECHA has taken the information provided into account and concluded that it is insufficient for demonstrating that the conditions of Annex XI, Section 1.2 of the REACH Regulation are met. ECHA notes that the information provided by the third party is not sufficient for concluding that the "human health" properties of the registered substance could be reliably predicted with tests performed with the read across substances shown. More specifically, the proposed weight-of-evidence approach is not sufficient to assume that the substance has or has not a particular dangerous property and that the standard information requirements for "90-day repeated dose toxicity, pre-natal developmental toxicity or reproductive toxicity studies" could be adapted. Although ECHA recognises that the information as provided by the third party might be scientifically valid, it does not fulfil Annex XI requirements and is therefore not sufficient to allow ECHA to reject the testing proposal.

In addition, the third party has explicitly mentioned that alkenes have been considered in the OECD SIDS higher olefin category. However, the existence of this category, or its consideration by the OECD, is not in itself a valid basis for adaptation of the information requirement.

Furthermore, insofar as these third party comments address read-across, ECHA notes that the testing plan for the higher olefins category is consistent with the third parties considerations and uses supporting data in a weight-of-evidence approach for consolidating the category.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the substance subject to this decision.

2. Pre-natal developmental toxicity study

a) Examination of the testing proposal

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

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, 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 generate the data for this endpoint.

The Registrant did not specify the species and route to be used for testing. 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 rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

ECHA did not receive information from third parties.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following study: Pre-natal developmental toxicity study in rat or rabbit, oral route (test method: EU B.31/OECD414) using using the substance subject to this decision.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

3. Timeline for providing the requested information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3 of the REACH Regulation. As the testing proposal for this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

The process of evaluation 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 evaluation of the testing proposals. 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.

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 grades registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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.

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