EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114308332-63-01/F Helsinki, 15 September 2015

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

For 3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate, oligomers, reaction products with 2-butanone oxime, EC No 500-287-7 (CAS No 103170-26-9), 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 proposal in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for 3-Isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate, oligomers, reaction products with 2-butanone oxime, EC No 500-287-7 (CAS No 103170-26-9), submitted by [redacted] (Registrant).

Repeated dose toxicity after inhalation exposure

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 4 July 2015, i.e. 30 calendar days after the end of the commenting period.

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 proposal for further examination pursuant to Article 40(1) on 27 May 2013.

ECHA held a third party consultation for the testing proposal from 12 December 2014 until 27 January 2015. ECHA did not receive information from third parties.

On 28 April 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.

On 3 June 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, the deadline in Section II was amended. Futhermore section III was changed.

On 23 July 2015 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 test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD 413) in rats. The test shall be performed using nose-only exposure and shall include bronchoalveolar lavage (BAL) analysis.

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 in this decision, or to fulfil otherwise the information requirements 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 **22 March 2018** 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 proposal submitted by the Registrant for the registered substance.

Tests required pursuant to Article 40(3)

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

A. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD 413) in rats

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 has submitted a testing proposal for a sub-chronic toxicity study (90 day) by the inhalation route (OECD 413).

ECHA acknowledges that the inhalation route is an appropriate route of administration for testing because human inhalation exposure is likely due to the spray application. ECHA notes that the substance is a solid with a low assumed oral bioavailability and that there is concern on local respiratory effects due to the findings of an inhalation subacute study.

Therefore, ECHA agrees with the Registrant that the inhalation route is the most appropriate route of administration for testing to fulfil the standard information requirement for Annex IX, Section 8.6.2.

The Registrant proposed testing in rats. According to the test method OECD 413 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

ECHA notes that significant findings were observed in the bronchioalveolar lavage (BAL) analysed in the subacute inhalation toxicity study. Hence ECHA is requesting that BAL is being performed in the inhalation 90-day (sub-chronic) study. BAL fluid shall be analyzed for total and differential cell count, protein content and lactate dehydrogenase. Other parameters should be considered by the Registrant taking into account potential effects of the substance in the lung. The Registrant should further consider that the preferred mode of exposure is nose-only and that particulate materials should be subjected to mechanical processes. Particle sizing should be performed for all aerosols that may condense to form aerosols. To allow for exposure of all relevant regions of the respiratory tract, aerosols with mass median aerodynamic diameters (MMAD) ranging from 1 to 3 µm with a geometric standard deviation (σg) in the range of 1.5 to 3.0 are recommended as specified in OECD 413 test guideline.

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: Sub-chronic toxicity study (90-day) in rats, inhalation route (test method: OECD 413). The test shall be performed using nose-only exposure and shall include bronchoalveolar lavage (BAL) analysis.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In his comments on the draft decision of 3 June 2015, the Registrant requested an extension of the timeline to 30 months. He justified this request by conducting this test as part of a grouping approach for blocked diisocyanate trimers. Furthermore, the registrant proposed extended recovery times of three months, an increased number of histopathological investigations, and investigation of the interrelationship of the study results of this and the other blocked diisocyanate compound. Taken together, these arguments are adequate for the requested deadline extension. Therefore, ECHA has granted the request and set the deadline to 30 months.

IV. 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 study meets 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.

In relation to the proposed test, the sample of substance used for the new study 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 test 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 the substance tested in the new study 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 study 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.

V. 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[1] by Claudio CARLON, Head of Unit, Evaluation

[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.