Decision number: TPE-D-2114299941-34-01/F Helsinki, 7 May 2015

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

For 1,3-Benzenedimethanamine, N-(2-phenylethyl) derivs., CAS No 404362-22-7 (EC No 445-790-1), 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 submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 1,3-Benzenedimethanamine, N-(2-phenylethyl) derivs., CAS No 404362-22-7 (EC No 445-790-1), submitted by [redacted]

Sub-chronic toxicity study in rats via inhalation route (aerosol) according to OECD 413.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes per year. This decision does not take into account any updates after 5 March 2015, 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.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 21 March 2014.

ECHA held a third party consultation for the testing proposal from 4 April 2014 until 20 May 2014. ECHA did not receive information from third parties.

On 19 September 2014 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 October 2014 ECHA received comments from the Registrant on the draft decision.

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

On 5 March 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 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 (aerosol) in rats (Annex IX, Section 8.6.2.; test method: OECD 413).

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 **14 November 2016** 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.

A. Tests required pursuant to Article 40(3)

> Sub-chronic toxicity study (90-days), inhalation route (aerosol) in rats (Annex IX, Section 8.6.2.)

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

In the registration dossier, an oral short-term repeated dose toxicity study (28-days) is available to fulfill the information requirement of Annex VIII, Section 8.6.1.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90-days) in rats via inhalation (aerosol) according to OECD 413 with the following justification: "*The conduct of a subchronic inhalation study with the rat is proposed based on BAUA communication no. 03 04 1579 00 from August 25, 2008 ([...]). BAUA conclude in their worker safety assessment that in manual spray application workers are getting exposed to the substance at concentrations < 2mg/cu.m air (without respiratory protection) and that therefore relevant inhalation exposure is given for workers.*"

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 registration dossier is currently at the tonnage level of 10 to 100 tonnes per year (Annex VIII), where the sub-chronic toxicity study (90-days) is not a standard information requirement. Consequently, in the draft decision sent to the Registrant for comments, ECHA rejected the sub-chronic toxicity study (90-days) by inhalation and requested performance of a short-term repeated dose toxicity study (28-day) by inhalation. In the comments to the draft decision, the Registrant justified performing the sub-chronic toxicity study (90-days) already at this tonnage level by stating: "*the tonnage of 1,3-Benzenedimethanamine, N-(2-phenylethyl) derivs (Gaskamine 240) is currently close to 100 t/a and thus a further upgrade of the dossier is anticipated for the next year. Thus, the test to be conducted should also comply with the information requirements for 100-1000 t/a. ... In case of the anticipated tonnage upgrade, the sub-chronic study will be required according to Annex IX, 8.6.2., column 1 and at the same time the short term toxicity study can be waived according to annex IX, section 8.6.1, column 1.* [redacted] *thinks thus, that the original testing proposal on a 90-day study should be maintained. [...] Consider that performing both tests should be avoided for reasons of animal welfare and costs.[...]*"

In addition to the information obtained from the testing proposal, the Registrant has submitted an inquiry to ECHA on 5 December 2014 concerning an expected increase in the tonnage band.

Based on the above mentioned reasons, ECHA expects the Registrant to update the dossier in the near future, and, on this basis, accepts the proposal to perform the sub-chronic toxicity study (90 day).

ECHA notes that the registered substance is a liquid at ambient temperature of low vapour pressure. In the technical dossier and/or chemical safety report uses with spray application are reported that may generate aerosols of inhalable size. Therefore, ECHA agrees with the Registrant that the inhalation route is an appropriate route of administration for testing and testing of the substance as aerosol is required.

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.

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: sub-chronic toxicity study (90 day) in rats, inhalation route (aerosol) (test method: OECD 413).

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 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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of 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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

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

[redacted]
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