EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114292057-46-01/F Helsinki, 22 January 2015

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

For (phenylethyl)benzene, CAS No 38888-98-1 (EC No 254-179-7), 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 (phenylethyl)benzene, CAS No 38888-98-1 (EC No 254-179-7), submitted by [redacted] (Registrant).

- Developmental toxicity / teratogenicity study (OECD 414) in the rat, via the oral route

This decision is based on the registration dossier 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 30 October 2014, 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.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 15 May 2013.

ECHA held a third party consultation for the testing proposal from 21 March 2014 until 5 May 2014. ECHA did not receive information from third parties.

On 11 August 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 15 September 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision and commenting on a screening study for teratogenicity to be found in the dossier.

The ECHA Secretariat considered the Registrant's comments and modified the Statement of Reasons (Section III) accordingly, whereas no amendments to the Information Required (Section II) were made.

On 30 October 2014 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:

> 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 **29 January 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.

Tests required pursuant to Article 40(3)

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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 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 in rats according to EU B.31/OECD 414. The Registrant submitted the following justification for testing:
"In summary, no (non-maternal mediated) developmental effects were seen in any of these well conducted studies with 1,1 –DPE [note by ECHA: trade name for the registered substance subject to the present decision or (phenylethyl)benzene] *and SAS-296 note by ECHA: mixture formed of registered substance not registered under REACH]. Even though for PTE developmental effects have been observed there is not enough substantial evidence for classification of 1,1`-DPE as developmental toxicant since data from screening assays with 1,1`-DPE and SAS-296 do not support the assumption for any developmental potency.*

The dossier does not currently have a pre-natal developmental toxicity study. Therefore, there is data gap for this endpoint. This the reason why the dossier contains a testing proposal for pre-natal developmental toxicity."

The dossier contains two OECD 422 screening studies on read-across substances. Furthermore, the Registrant provided in the endpoint summary a screening study on the registered substance.

One of the analogue read-across substances (PTE: trade name for Phenyl-tolyl-ethane, CAS No 40766-30-1) shows clear toxicity (maternal toxicity, as well as increased pup mortality at the top dose as well as reduced pup weights in the mid-dose) which warrants classification of PTE as Repr. 1B in accordance with Regulation (EC) No 1272/2008.

However, the Registrant has not applied the classification as Repr. 1B to the registered substance subject to the present decision, using as argument the results from a second study on the analogue substance 1,4-dimethyl-2-(phenylethy)benzene and a screening study on the registered substance. Nevertheless, the results obtained with the two read-across substances and on the registered substance subject to the present decision confirm the need to obtain information on developmental toxicity besides the acknowledged data-gap in the current dossier for this endpoint as indicated in the Registrant's justification.

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 in rats. He 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.

b) Outcome

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).

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.

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 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 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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