ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114299843-32-01/F Helsinki, 8 May 2015

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

For 4-morpholinecarbaldehyde, CAS No 4394-85-8 (EC No 224-518-3), 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[s] submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 4-morpholinecarbaldehyde, CAS No 4394-85-8 (EC No 224-518-3, submitted by [redacted] (Registrant).

- 90-day oral toxicity study (OECD 408) in rats, oral route

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of [redacted] 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.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 21 May 2013.

ECHA held a third party consultation for the testing proposal from 4 April 2014 until 19 May 2014. ECHA did not receive information from third parties.

On 11 November 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. That draft decision was based on submission number [redacted].

On 25 November 2014 the Registrant updated his registration dossier with the submission number [redacted]

On 26 November 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments.
On basis of this information, Section III was amended. whereas no amendments to the Information Required (Section II) were made.

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 following additional test pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

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

while the originally proposed test for a Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats proposed to be carried out using the registered substance is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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 sound 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 Authorities of the Member States for possible enforcement.

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 **15 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-day), inhalation route (Annex IX)

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

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) in rats via the oral route (OECD 408). The Registrant considers that oral route is appropriate due to the low vapour pressure of the registered substance. However, ECHA considers that the proposed study via the oral route is not appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation, because the proposed route is not the most appropriate route of administration having regard to the likely route of human exposure.

According to Annex IX 8.6.2. Column 2 testing via inhalation is appropriate if the exposure to humans is likely via aerosols, particles or droplets of an inhalable size. In the IUCLID dossier, the Registrant mentions industrial, professional and consumer uses with PROCs including spray applications. The Registrant states for exposure scenario ES 9 (PROC 7), that the registered substance is used in concentration of [redacted]% for spraying application without respiratory tract protection. Thus, any possible local effects to respiratory tract should also be taken into account. The only inhalation study available in the dossier is an acute study which is not suitable to assess local effects, because the substance has a low vapour pressure and was tested only up to vapour saturation without any effect seen in the animals. The registered substance contains an aldehyde group connected to the nitrogen atom. This is a carboxamide functional group in a cyclic structure. Therefore, ECHA notes that this structure might indicate a potential chemical reactivity towards the respiratory tract, thus possible local effects via inhalation route. Based on all the arguments above ECHA is of the opinion that the inhalation route is the most appropriate route of administration for the testing.

In the comments to the draft decision, the Registrant agreed to test the registered substance via the inhalative route of exposure based on the uses and spraying application especially.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the following study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, inhalation route (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.

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]
Ofelia Bercaru
Head of Unit, Evaluation