

Decision number: TPE-D-0000001974-66-03/F

Helsinki, 5 April 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For Diisopropylamine, CAS No 108-18-9 (EC No 203-558-5), 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 a testing proposal set out in the registration dossier for diisopropylamine, CAS No 108-18-9 (EC No 203-558-5) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for a substance registered in quantities between 10 and 100 tonnes per year. The substance is registered as a transported isolated intermediate, according to Article 18 of the REACH Regulation, in quantities [REDACTED] and as an on-site isolated intermediate, according to Article 17 of the REACH Regulation, in quantities [REDACTED].

In accordance with Articles 10(a)(ix) and 12(1)(d) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX:

Annex IX, 9.2.1: Further biotic degradation testing, (Simulation Test - Aerobic Sewage Treatment.)

The examination of the testing proposal was initiated on 28 September 2010.

On 27 September 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 27 October 2011 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 January 2012 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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 requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage and is without prejudice to the fulfilment of the conditions required for registration of transported isolated and on-site isolated intermediates.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method:

Further biotic degradation testing, (Simulation Test - Aerobic Sewage Treatment. (Annex IX, 9.2.1, test method: EU C.10/OECD 303A)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **5 April 2013** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance. The proposed test is not available in the registration dossier. According to Article 40(3)(a) ECHA may require the Registrant to carry out the proposed test.

The chemical safety report (CSR) of the registration dossier indicates that there is a risk associated with the sewage treatment plant (STP) (as specified in CSR, section 10.1.2.4). According to Annex 1, section 6 of the REACH Regulation if the risk characterisation ratio (RCR) exceeds 1 and indicates a risk to the environment, then it is necessary to carry out an iterative process with amendment of one or a number of factors in the hazard or exposure assessment with the aim to demonstrate adequate control. This may require generation of additional information. The proposed test (test method: EU C.10/OECD 303A) is suitable to generate such information and to refine the predicted environmental concentration (PEC). This is acknowledged by the ECHA Guidance which states that even though activated sludge simulation tests such as the proposed test are not a standard information requirement under the REACH Regulation they can be used to refine the PEC and may help to determine whether either simulation tests are required or which simulation test may be the most relevant (Guidance on Information Requirements and Chemical Safety Assessment R7b, page 210).

Therefore the proposed test is considered as an appropriate further biotic degradation test. Moreover, it may allow determining whether further simulation tests as specified under Annex IX, 9.2.1 are required. Consequently, the Registrant is required to perform the proposed test pursuant to Article 40(3)(a) of the REACH Regulation.

If conducting the proposed test identifies the need to perform further degradation testing, the Registrant shall submit a new testing proposal(s) to address this as appropriate.

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 generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, 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 the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.

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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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