ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000001945-67-03/F Helsinki, 29 March 2012

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

For [redacted] [203-612-8] hexahydro-1,3,5-trimethyl-1,3,5-triazine, CAS 108-74-7 (EC No 203-612-8), 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 hexahydro-1,3,5-trimethyl-1,3,5-triazine CAS 108-74-7 (EC NO 203-612-8) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes per year.

In accordance with Articles 10(a)(ix) and 12(1) (e) 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, 8.4: Genetic toxicity

EU Method B.12 (Mutagenicity - *In Vivo* Mammalian Erythrocyte Micronucleus Test) or the equivalent OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 09/08/2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 11/1/2011 until 25/2/2011. ECHA received no comments from third parties.

On 28 September 2011 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 26 October 2011 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received and did amend the draft decision.

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.

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:

EU Method B.12 (Mutagenicity - *In Vivo* Mammalian Erythrocyte Micronucleus Test)

or the equivalent OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **02/04/2013** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance.

Pursuant to Article 40(3)(a) of the REACH Regulation ECHA may take a decision to require the Registrant to carry out the proposed test and setting a deadline for the submission of the requested information.

The Registrant has proposed to confirm whether hexahydro-1,3,5-trimethyl-1,3,5-triazine is clastogenic causing structural and numerical chromosome aberrations *in vivo* by performing an *in vivo* mammalian erythrocyte test in accordance with EU Method B.12 "Mutagenicity - *In Vivo* Mammalian Erythrocyte Micronucleus Test". This guideline is equivalent to OECD TG 474.

The registered substance has been tested positive in an *in vitro* Mammalian Chromosome Aberration Test (OECD Guideline 473). According to REACH Annex IX 8.4 Column 2, if there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the Registrant. The dossier contains no *in vivo* studies.

ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R7a Endpoint Specific Guidance mentions rodent bone marrow or mouse peripheral blood micronucleus test (OECD TG 474) or a rodent bone marrow clastogenicity study (OECD TG 475) as alternatives for a somatic cell genotoxicity test.

Therefore, ECHA agrees with the registrant's proposal to conduct a study with hexahydro-1,3,5-trimethyl-1,3,5-triazine in an *in vivo* Mammalian Erythrocyte Micronucleus Test.

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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 always 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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