EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002095-79-03/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 PROPYLIDYNETRIMETHYL TRIMETHACRYLATE, CAS No 3290-92-4 (EC No 221-950-4), 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 propylidynetrimethyl trimethacrylate, CAS No 3290-92-4 (EC No 221-950-4), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

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

Long-term toxicity testing on fish (OECD guideline 210 Fish, Early-Life Stage Toxicity Test)

The examination of the testing proposal was initiated on 24 November 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 1 July 2011 until 15 August 2011. ECHA did not receive any comments from third parties.

On 16 November 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.

By 16 December 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.

II. Testing required

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

- Long-term toxicity testing on fish (Annex IX, 9.1.6, OECD guideline 210 Fish, Early-Life Stage Toxicity Test)

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.

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.

Long-term aquatic toxicity test is a standard information requirement as laid down in Annex IX, section 9.1.6 conditional to a need indicated by the chemical safety assessment according to column 2 of Annex IX, section 9.1. 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. ECHA notes that, despite no explicit reason is provided in the technical dossier why the testing proposal was submitted, the Registrant has deemed the test necessary in order to further study the effects on aquatic organisms. ECHA notes further that the acute aquatic toxicity data available indicates fish as the most sensitive species. Furthermore the Registrant states that as only acute toxicity data are available, a high assessment factor is applied when deriving the presumed no-effect concentrations. ECHA also notes that the acute toxicity tests have been performed close to the water solubility limit and that some of the risk characterisation ratios for the aquatic environment are close to one. Having regard to the above considerations, ECHA concludes that the proposed test is tailored to real information needs and it is necessary to generate the data for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed: Fish, Early-Life Stage Toxicity Test (test method: OECD 210).

IV. 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.

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://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.

[redacted]

Jukka Malm
Director of Regulatory Affairs