European Chemicals Agency

Decision number: TPE-D-0000001608-71-03/F Helsinki, 28/09/2011
Decision date: 28 September 2011

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

**For Reaction product of ammonium molybdate and C12-C24-diethoxylated alkylamine (1:5-1:3), EC No. 412-780-3, 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 testing proposals set out in the registration dossier for **Reaction product of ammonium molybdate and C12-C24-diethoxylated alkylamine (1:5-1:3), EC No 412-780-3** submitted by [redacted] (Registrant), latest submission number [redacted], for [redacted]

The Registrant notified the substance pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the French competent authority in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was [redacted]

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

In accordance with Articles 10(a)(ix) and 12(1) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier:

a) Annex IX, 9.4.1 Toxicity to soil macro-organisms except arthropods according to OECD Guideline 207 (Earthworm, Acute Toxicity Tests), and

b) Annex IX, 9.4.3 Toxicity to terrestrial plants according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test)

The testing proposal examination was initiated on 30 September 2010.

On 29 March 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.

On 27 April 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and did not amend the draft decision.

On 17 June 2011, 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. 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 REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Information required

Pursuant to Article 40(3)(a) or (b) of the REACH Regulation, the Registrant shall carry out the following tests and submit respective robust study summaries:

a) ***Long-term toxicity to terrestrial invertebrates*** (Annex IX, 9.4.1. column 2 REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) earthworm reproduction test (OECD guideline 222) or ***short-term toxicity to terrestrial invertebrates*** (Annex IX, 9.4.1. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) earthworm acute toxicity test (EU Method C.8/OECD guideline 207); and
b) ***Long-term toxicity on terrestrial plants*** (Annex IX, 9.4.3. column 2 REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) (ISO standard 22030) or ***short-term toxicity on terrestrial plants*** (Annex IX, 9.4.3. REACH Regulation; Annex VIII, level 1 Directive 67/548/EC) seedling emergence and seedling growth test (OECD guideline 208/ ISO standard 11269-2).

Pursuant to Article 3(28) of the REACH Regulation, robust study summaries to be prepared for the studies indicated above shall contain sufficient information, including information on the test material identity, to make an assessment of the relevance of the studies. This is also in line with the OECD test guidelines indicated above. Among information on test material, the composition of the registered substance shall be given in such a detail that

- all constituents > 10% (w/w) or relevant for classification and labelling and/or PBT assessment are identified;
- every known constituent is reported;

- constituents which are unknown are identified as far as possible by a generic entry describing their chemical nature.

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by 28 September 2012 an update of the registration containing the information required by this decision.

III. Statement of reasons

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

Articles 10(a)(ix) and 12(1)(c) as well as Annexes VI to VIII to the REACH Regulation lay down the minimum information requirements for substances registered at the present tonnage level ([redacted]). In addition, since the registration is based on a notification pursuant to national legislation implementing Directive 67/548/EEC, the information requirements should not be stricter than those under that Directive.

ECHA notes however that the Registrant has in relation to the assessment of the P (persistent) and B (bioaccumulative) properties of the substance concluded that substance is highly adsorptive and potentially very persistent and proposes to generate further information to refine the risk assessment. More specifically, the Registrant has identified the need to further investigate the effect of the substance in the soil environment. As the information on these endpoints is indicated as needed by the Registrant and it will not involve testing on vertebrates ECHA considers that it is necessary to generate the data and to perform the proposed tests.

ECHA points out that as the registered substance is highly adsorptive and supposedly persistent long-term tests should be preferred in analogy to column 2 of section 9.4 of Annex IX to the REACH Regulation. Therefore, the Registrant should preferably perform a (long-term) earthworm reproduction test (OECD guideline 222) and a long-term toxicity test on plants (ISO standard 22030). The Registrant is also requested to submit respective robust study summaries.

The material which was tested needs to be clearly identified in the robust study summaries to be made based on the tests to be performed as the registered substance is a complex UVCB substance. The OECD test guidelines indicate request to include the definitive description of the test material or chemical identification data in a full study report so this information should be available for the Registrant.

IV. 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 reads:

> "Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

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 the technical progress and use the applicable test methods to generate the information on the endpoints indicated above.

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

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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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.

Done at Helsinki,

Jukka Malm
Director of Regulatory Affairs