ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002378-69-03/F Helsinki, 14 May 2012

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

**For [redacted]hydroxy-substituted alkanoate, CAS No [redacted] (EC No [redacted]), registration no [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 testing proposals set out in the registration dossier for [redacted]hydroxy-substituted alkanoate, CAS No [redacted] (EC No [redacted]), submitted by [redacted] (Registrant), latest submission no. [redacted], for the tonnage band of 10 to 100 tonnes per year.

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:

- Dissociation constant (OECD Guideline 112 (Dissociation Constants in Water)).

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 7 June 2011.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 29 July 2011 until 12 September 2011. ECHA did receive information from third parties.

On 2 December 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. The draft decision referred to submission number WU259763-91.

On 22 December 2011 the Registrant provided to ECHA comments on the draft decision and on 26 January 2012 the Registrant updated his registration dossier (submission number MV292416-03) removing two of the three previously submitted testing proposals.

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

On 2 March 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 from initiating 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 and the registered substance:

Dissociation constant, Annex IX, 7.16. (test method: OECD 112).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **14 November 2012** 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 submitted by the Registrant for the registered substance.

**Dissociation constant**

Pursuant to Article 40(3)(a) ECHA may require the Registrant to carry out the proposed test.

Dissociation constant is a standard information requirement as laid down in Annex IX, 7.16. of the REACH Regulation. The information on this endpoint is not available for the registered substance but this is a standard information requirement for substances registered for 100 tonnes or more per year whereas the current dossier covers only the tonnage band 10 – 100 tonnes per year. However, the Registrant identified a need for testing concerning this endpoint: "[redacted]" Based on the justification for the study provided by the Registrant, considering that Article 12(1)(c) establishes *minimum* information requirements and taking into account that no vertebrate animals are involved, ECHA concludes that the test shall be performed pursuant to Article 40(3)(a) of the REACH Regulation.

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 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