

Decision number: TPE-D-0000002083-84-03/F Helsinki, 12 March 2012

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

For Tetraethyl lead, CAS 78-00-2 (EC No 201-075-4), 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 Tetraethyl lead, CAS No 78-00-2 (EC No 201-075-4), 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 proposal as part of the registration dossier to fulfil the information requirements set out in Annex IX:

Annex IX, 7.17: Viscosity.

The examination of the testing proposal was initiated on 8 December 2010.

On 17 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.

On 16 December 2011 ECHA received comments from the Registrant stating that the registrant would like to waive the viscosity endpoint. ECHA considered the Registrant's comments received and amended the draft decision by extending section III. Statement of reasons.

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:

- Viscosity (Annex IX, 7.17, OECD Test method 114).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **12 September 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 of the Registrant for the registered substance.

According to Article 10(a)(vi) and Annex IX, viscosity data must be included in the dossier. As the dossier does not contain adequate information on the viscosity of the substance there is a data gap for this endpoint which must be filled by data from a valid test.

The Registrant commented the draft decision by proposing to waive the viscosity endpoint stating that the existing classification (Acute Tox. 1 (oral, dermal and inhalation)) would supersede any possible classification for aspiration hazard. ECHA notes that the proposed waiving argument cannot be considered valid because the classification as toxic does not supersede a classification for the aspiration hazard under Regulation (EC) No 1272/2008 (CLP Regulation). In addition, viscosity is a standard information requirement in Annex IX of the REACH Regulation regardless of whether it would lead to classification for aspiration hazard or not.

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 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.

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 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.



Jukka Malm
Director of Regulatory Affairs