



For final decision: TPE-D-0000001361-85-03/F

Helsinki, 16 February 2011

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

For **5,5-DIMETHYLHYDANTOIN, SODIUM SALT, CAS 54807-34-0 (EC No 476-160-4)**,
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 **5,5-dimethylhydantoin, sodium salt, CAS no. 54807-34-0 (EC no. 476-160-4)**, Registration number: [REDACTED] submitted by [REDACTED] (the "Registrant"), latest submission number [REDACTED] for 100-1000 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:

Annex IX, 7.16 Dissociation constants in water (OECD Test Guideline 112);

The examination of the testing proposal was initiated on 04 May 2010.

On 17 September 2010 ECHA sent a draft decision to the Registrant.

By 18 October 2010 ECHA received no comments on the draft decision from the Registrant.

On 29 October 2010 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. By 28 November 2010 ECHA did not

receive any proposals for amendments from the competent authorities of the Member States.

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. Testing required

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

Annex IX, 7.16 Dissociation constants in water (OECD Test Guideline 112);

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by 6 months from the date of the decision, i.e. on 16 August 2011 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 proposal of the Registrant for the registered substance.

The proposed test referred to in Section II above is part of the information requirements as laid down in Annex IX of the REACH Regulation. As the information on this endpoint is not available for the registered substance but need to be present in the technical dossier to meet the information requirements it is necessary to generate the data and to perform the test.

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.”

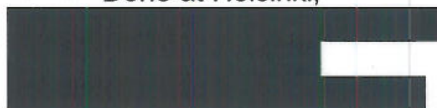
According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate.

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.

Done at Helsinki,



Jukka Malm
Director of Regulatory Affairs