

Helsinki, 13 June 2012

Decision number: TPE-D-0000001898-58-05/F

**DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION
PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006****For Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts
(2:1),
CAS [REDACTED], registration number: [REDACTED]****Addressee:** [REDACTED]
[REDACTED]
[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 **Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1) CAS [REDACTED]** submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1000 tonnes 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, 7.16: Dissociation Constant
OECD Guideline 112 (Dissociation Constants in Water)

The examination of the testing proposal was initiated on 05/10/2010.

On 31 October 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.

By 1 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.

Subsequently, one Competent Authority of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify the draft decision.

On 23 February 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals within 30 days of the receipt of the notification.

On 27 February 2012 the Registrant provided comments on the proposals for amendment.

On 5 March 2012, the draft decision was referred to the Member State Committee. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

The Member State Committee reached unanimous agreement on the draft decision in a written procedure launched on 28 March and closed on 11 April 2012.

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:

- Dissociation Constant (Annex IX, 7.16, OECD Guideline 112)

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 13 December 2012** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The proposed test (Dissociation Constant) referred to in Section II is part of the information requirements as laid down in Annex IX 7.16 of the REACH Regulation. As the information on this endpoint is not available, but needs to be present in the technical dossier to meet the information requirements, it is necessary to generate data performing a study according to OECD Guideline 112 using the registered substance as the test material.

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