~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001355-78-03/F Helsinki, 21 March 2011

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For [redacted] **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 41(1) of the REACH Regulation, ECHA has performed a compliance check of the registration dossier for [redacted] submitted by [redacted] (the "Registrant"), latest submission number [redacted] for 1-10 tonnes per year.

The compliance check was initiated on 2 July 2010.

On 16 September 2010 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 12 October 2010 the Registrant provided to ECHA comments on the draft decision, including the intention to update the dossier without target date. ECHA has considered the information received and decided to amend the draft decision.

On 18 November 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. Subsequently, Competent Authorities of the Member States submitted comments, which did not include proposals for amendments on the draft decision. Following Article 51(3) of the REACH Regulation, ECHA

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has therefore taken the decision concerning the present compliance check as notified to the Member State Competent Authorities and issued on 18 November 2010.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(a) and Annex VII of the REACH Regulation the Registrant shall submit an updated robust study summary for skin sensitisation

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10(a)(vi), 12(1)(a) and Annex VII thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

More specifically, information related to the skin sensitisation endpoint (REACH Annex VII, 8.3.) is missing. Pursuant to Articles 10(a)(vi) and 12(1)(a) of the REACH Regulation, a registration for a substance produced in quantities 1-10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

REACH Annex VII requires the Registrant to submit information on skin sensitisation and any other relevant information that is available. The Registrant has submitted information on skin sensitisation obtained by Guinea pig maximisation test (OECD testing guideline 406). The OECD 406 testing guideline requires that in the induction phase mild-to-moderate skin irritation should be caused. If the substance itself is not a skin irritant, the test area "is painted with 0.5 ml of 10% sodium lauryl sulphate in Vaseline in order to create a local irritation" 24 hours before the topical induction application. According to information submitted by the Registrant the substance is not irritating to skin in rabbit and the Registrant has not submitted any information that would indicate the substance to be irritating to skin in Guinea pig either. Therefore, in the induction phase the skin should have been painted with sodium lauryl sulphate prior to topical application of the test substance. However, on 12 October 2010 ECHA received a letter in which the Registrant explains that the treatment with sodium lauryl sulphate in Vaseline was carried out prior to topical induction application, even though this information could not been found in the dossier. ECHA considers that the test is acceptable and expects the Registrant to submit an updated IUCLID dossier.

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:

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"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 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 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. The procedure is described in the Board of Appeal's "Preliminary instructions to Appellants" that can be found at the ECHA website. 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,

[redacted]

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Director of Regulatory Affairs

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