~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001813-76-02/F Helsinki, 20 December 2011

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

For [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 (the 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] (the "Registrant"), latest submission number [redacted]

The Registrant notified the substance pursuant to the national legislation implementing of Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) and its Article 7 by submitting a notification to the [redacted] Competent Authority. The notification number allocated was [redacted]

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

[redacted] Thus, the dossier may not include some relevant legally required information. For that reason, ECHA invited the Registrant by letter of 27 August 2009 to update the dossier and submit testing proposals, if necessary, to bring the registration into compliance with the information requirements of the REACH Regulation. However, no testing proposal or updated dossier has been received by the date the compliance check was initiated.

The compliance check of this dossier was initiated on 20 April 2010.

On 20 April 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.

On 12 May 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received but found no need to amend the draft decision.

On 17 June 2011 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 proposals for amendment to the draft decision.

On 20 July 2011 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 within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and modified the draft decision accordingly.

On 1 August 2011 ECHA referred the draft decision to the Member State Committee.

By 19 August 2011 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 2 September 2011 in a written procedure launched on 22 August 2011.

This 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) and (vii), 12(1)(d) and 13, as well as Annexes VII, VIII and IX of the REACH Regulation, the Registrant shall submit the information using the test methods as indicated below.

a) *In vitro* gene mutation study in bacteria [redacted], EU test method B13/14 or OECD 471; and
b) Pre-natal developmental toxicity study (Annex IX, 8.7.2. of the REACH Regulation and [redacted] one species, oral route, EU test method B.31 or OECD 414.

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 20 December 2012.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant in course of the earlier notification and now subject to the requirements of the REACH Regulation, does not comply with the requirements of Articles **10, 12 and 13 of the REACH Regulation and with Annexes VII, VIII and IX** thereof.

Since the registration is not a tonnage band upgrade, it does not have to comply with all of the information requirements of the relevant tonnage band level of the REACH Regulation (Article 24(2) of the REACH Regulation). This Article indicates that a registration originating from a previous notification and in those cases other than a tonnage band upgrade needs to comply with the information requirements of the REACH Regulation limited by the scope of information requirements pursuant to Directive 67/548/EEC, depending on which regulatory framework requires less information. The information requested (see section II above) is covered by both the REACH Regulation and Directive 67/548/EEC.

The technical dossier provided did not contain information for the endpoints on:

[redacted] *in vitro* gene mutation study in bacteria (requirement of [redacted]

An *in vitro* gene mutation study in bacteria is required under [redacted]. 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.

ECHA notes that information on an *in vitro* gene mutation study in bacteria, using four *Salmonella typhimurium* strains, has been submitted. [redacted]

In his comments, the Registrant proposed a different strategy for mutagenicity testing that would not involve [redacted] ECHA reviewed the further information received but found no need to amend the draft decision, observing that information with [redacted]

ECHA would also like to point out that no information on an *in vitro* gene mutation study in mammalian cells has been submitted. According to Annex VIII, section 8.4.3 of the REACH Regulation, the *in vitro* gene mutation study in mammalian cells is required if there is a negative result in the *in vitro* studies specified under Annex VII, section 8.4.1 and Annex VIII, section 8.4.2, and if adequate and reliable data from an *in vivo* mammalian gene mutation test are not available. ECHA therefore reminds the Registrant that, if the results of the *in vitro* gene mutation test on bacteria [redacted] will be negative, an *in vitro* gene

mutation study in mammalian cells according to EU test method B.17 or OECD 476 shall be performed according to REACH, Annex VIII 8.4.3. [redacted]

Furthermore, if the result of the *in vitro* gene mutation test in bacteria performed [redacted] as described above is positive, ECHA invites the Registrant to consider appropriate *in vivo* mammalian gene mutation tests in accordance with Annex VIII, section 8.4.

[redacted] Pre-natal developmental toxicity study (Annex IX, 8.7.2. of the REACH Regulation [redacted]

A pre-natal developmental toxicity is a requirement of both Annex IX, 8.7.2 of the REACH Regulation [redacted] but information on this endpoint is missing. The Registrant is accordingly requested to perform such a study (one species, oral route) according to OECD 414 or EU Method B.31.

ECHA also reminds the Registrant of the specific rules for adaptation in Annex IX, 8.7, column 2, which state that the pre-natal developmental study does not need to be conducted if the registered substance is known to be a germ cell mutagen, i.e. there is sufficient information for a decision to classify the registered substance as Mutagen Category 1B according to Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation), and appropriate risk management measures are implemented.

IV. General instruction on the update of dossiers of previously notified substances

Pursuant to Article 111 of the REACH Regulation, the requested information should be submitted to ECHA in the form of an IUCLID dossier update. Instructions on the submission of the dossier update can be found in the Question and Answers document for the registrants of previously notified substances published on the ECHA website on the following link: http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf. In addition the Data Submission Manual No 5, Annex 4, "Minimum information required for updating a registration under previous directive", in the section "Other updates", available at: http://echa.europa.eu/reachit/registration-it_en.asp should be consulted.

These reference documents include information on possible alternative means that can be used in place of robust study summaries i.e. that under certain circumstances study summaries can be sufficient when submitting a dossier update.

V. 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, 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.

VI. 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. 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]

Jukka Malm
Director of Regulatory Affairs