~~CONFIDENTIAL~~

European Chemicals Agency

Decision number CCH-D-0000001713-78-04/F Helsinki, 03/11/2011

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 (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] submitted by [redacted] (Registrant), latest submission number [redacted], for 100-1000 tonnes per year.

The Registrant notified the substance pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the German Competent Authority in accordance with Article 7 of Directive 67/548/EEC. 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.

The national Competent Authority did not finalise its assessment of the testing programme before the relevant Article 135 of the REACH Regulation entered into force on 1 August 2008. 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 of this decision.

The compliance check was initiated on 9 March 2010.

On 14 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 13 October 2010, 22 November 2010 and 21 December 2010 the Registrant provided to ECHA comments on the draft decision.

ECHA took into account the information received and amended 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 decided not to modify the draft decision.

On 29 July 2011 the Registrant provided comments on the proposals for amendment.

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

The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 20-23 September 2011, the draft decision was modified by the Member State Committee and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 22 September 2011.

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) and (vii), 12(1)(d) and Annex VIII of the REACH Regulation, the Registrant shall submit the information using the test method as indicated below for:

In vitro gene mutation study on mammalian cells (Annex VIII, 8.4.3. of the REACH Regulation; Annex VIII Level 1 of Directive 67/548/EEC, EU test method B.17)

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 3 August 2012.**

III. Statement of reasons

The registration was formerly a notification made in accordance with Directive 67/548/EEC. It follows from Article 24(2) of the REACH Regulation that a registration originating from a previous notification, in cases other than a tonnage band update, needs to comply with the information requirements of the REACH Regulation for the registered tonnage band or in the case the requirements of the REACH Regulation for that tonnage band are stricter than those set out in Directive 67/548/EEC, the registration needs to comply with the requirements of Directive 67/548/EEC for that tonnage band.

Based on the examination of the technical dossier, ECHA concludes that the information therein, does not comply with the requirements of Articles **10 and 12 and with Annex VIII** of the REACH Regulation.

The technical dossier for the registered substance does not contain any information for the endpoint mentioned under Section II. This information would have also been required for the same tonnage band under Directive 67/548/EEC. Consequently, the Registrant is requested to submit the information mentioned in Section II to bring the registration into compliance with the relevant information requirements.

In response to ECHA's draft decision sent on 14 September 2010 the Registrant provided the following information:

In vitro gene mutation test on mammalian cells.

The Registrant stated that there would be no legal basis to request a further test, namely the *In vitro* gene mutation study on mammalian cells. ECHA notes first, that this is a standard information requirement under the REACH Regulation, Annex VIII, 8.4.3. for substance registered at 10 tonnes or more per annum. Second, the requested test was a requirement under Directive 67/548/EEC that foresaw two tests at Annex VII, 4.3.1. ('base set') of Directive 67/548/EEC and a third test at Annex VIII, Level 1 *('When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the purposed use of the substance')*. Hence, if the *in vitro* gene mutation study on mammalian cells was not yet performed for the base set, it was required at the higher level and ECHA regards it as being part of the standard information requirement for substances notified previously under Directive 67/548/EEC for 10 tonnes or more per annum. In addition, the *in vivo* micronucleus study (that was provided in the dossier) does not address the ability to induce gene mutation in mammalian cells, because it covers only the chromosomal aberration and aneugenic potential. Therefore, the currently available results from the test battery on genotoxicity do not cover gene mutation in mammalian cells. Consequently, the testing is required.

Following the removal of the pre-natal developmental toxicity test following the Member State Committee deliberations a reduced time of nine months for providing the required information is considered to be appropriate.

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. You can find instructions on the submission of the dossier update in the Question and Answers document for the registrants of previous 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 we also advise you to consult 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.
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 1907/2008 as adapted to technical progress and use the applicable test methods to generate the information on the endpoints indicated above.

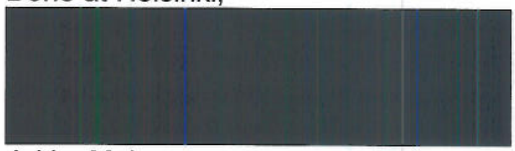
National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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,



Jukka Malm
Director of Regulatory Affairs