~~CONFIDENTIAL~~

European Chemicals Agency

For final decision: CCH-D-0000001559-66-04/F
Decision date: 1 July 2011

Helsinki, 1 July 2011

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

FOR [redacted] CAS [redacted] (EC Nr. [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] (EC Nr. [redacted]) submitted by [redacted] (the "Registrant"), latest submission number [redacted], for [redacted]

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 compliance check was initiated on 4 May 2010.

ECHA drafted a decision in accordance with Article 41 of REACH. On 12 November 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.

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

On 17 November 2010, the Registrant provided comments on the draft decision to ECHA via e-mail and on 8 December 2010 via the respective web-form. On 19 November 2010, the Registrant submitted an updated IUCLID dossier to ECHA. ECHA considered the information received and amended the draft decision accordingly.

On 17 March 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 amendments to the draft decision.

On 20 April 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 amendments received and decided to amend the draft decision.

On 2 May 2011, the draft decision was referred to the Member State Committee.
On 19 May 2011, the Registrant provided comments on the proposed amendments.

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

After discussion in the Member State Committee meeting on 25-27 May 2011, the Member State Committee modified the amended draft decision and a unanimous agreement of the Member State Committee on the modified and amended draft decision was reached on 27 May 2011.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, Section 2 of the REACH Regulation the registrant shall submit for the registered substance:

    - High-pressure liquid chromatogram or a gas chromatogram

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(a), 13 and Annex VII of the REACH Regulation the Registrant shall submit the information on:

    - Qualitative composition (including identity of the hydrolysis products of the substance) of the test solutions in the *Daphnia* and *Algae* toxicity tests performed; and
    - Toxic effect concentrations (acute EC50 values) of the hydrolysis products of the registered substance to *Daphnia* and *Algae* relevant for the interpretation of these aquatic toxicity tests submitted in the technical dossier as predicted by valid Qualitative or Quantitative Structure-Activity Relationship models ((Q)SARs) following the requirements of section 1.3 of Annex XI to the

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

REACH Regulation. Any other available relevant information on the intrinsic properties of the hydrolysis products shall be submitted.

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 **1 December 2011 - 6 months from the date of the decision**.

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, 12 and with Annex VI 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.

Following the tonnage band update to [redacted] for a substance previously notified under Directive 67/548/EEC, the Registrant is according to Article 24(2) of the REACH Regulation obliged to submit the additional required information corresponding to the reached tonnage threshold as well as to all lower tonnage thresholds in accordance with Articles 10 and 12 of the REACH Regulation.

1) Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation, the technical dossier of the registration shall include sufficient information to identify the registered substance.

According to Section 2.3.6 of Annex VI of the REACH-Regulation a high-pressure liquid chromatogram (HPLC) or a gas chromatogram (GC) is required to enable the substance to be identified and it was not provided in the Registrant's IUCLID registration dossier. Furthermore HPLC or GC inclusive information on the calibration and the quantitative evaluation is necessary and should be provided in the Registrant's IUCLID registration dossier to confirm the substance purity and composition. The justification provided in section 1.4 of the Registrant's IUCLID registration dossier "*neither GC nor HPLC analytik on tin compound performed in due to irreversible damage of column through the substance*" is not satisfactory as a HPLC method was applied on the substance in other tests, e.g. determination of the partition coefficient and estimation of the adsorption coefficient. Therefore a high-pressure liquid chromatogram or a gas chromatogram with inclusive information on the calibration and the quantitative evaluation (please attach this information in section 1.4 of the Registrant's IUCLID registration dossier) for the identification of the substance and impurities shall be provided.

2) Missing information related to endpoints

Pursuant to Articles 10(a)(vi), 12(1)(a) of the REACH Regulation, a registration for a substance produced in quantities of [redacted] shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

The results of the acute toxicity of the substance to *Daphnia magna* in a static 48-hour immobilisation test (REACH information requirement of Annex VII, 9.1.1.) are provided in

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

section 6.1.3 of the IUCLID registration dossier. The results of the toxicity of the substance to *Desmodesmus subspicatus* in an algal growth inhibition test (REACH information requirement of Annex VII, 9.1.2.) are provided in section 6.1.5 of the IUCLID registration dossier. Furthermore, new information provided in form of an update of the registration dossier on 19th November 2010 indicates that the substance hydrolyses immediately upon contact with water.

According to the information provided in the updated dossier on the exposure media used in the ecotoxicological tests, the substance was stirred for 24 hours to dissolve as much test item as possible and the undissolved test item was separated by filtration. Dilutions of the filtrate were further used in the ecotoxicological studies. For the determination of the substance in test samples in both ecotoxicological studies mentioned above the Total Organic Carbon (TOC) content was measured, which is a non-specific analytical method. Bearing in mind that the substance hydrolyses immediately upon contact with water it may be presumed that (a) hydrolysis product(s) were measured by TOC instead of the parent substance. It appears that the hydrolysis of the parent substance was not taken into account when performing ecotoxicological tests and that these test results cannot be further used for the classification and/or risk assessment of the substance as exposure and effect concentration(s) which are needed for that purpose cannot be reliably quantified. Therefore, ECHA concludes that the ecotoxicological studies submitted lack sufficient information since the composition (qualitative and quantitative) of the test solutions in these studies was not properly determined.

A repetition of the ecotoxicological tests mentioned above may not necessarily result in more reliable data. However, additional information on this type of fast hydrolysing and therefore difficult to test substance would allow for the better characterisation of the ecotoxicological properties of the registered substance. In the responses to ECHA's draft decision and the responses to the proposals received from the Member State Competent Authorities, the Registrant has provided additional information that could be useful in this regard. However, this information was not provided in the form of an updated dossier. Therefore the Registrant is requested to submit the information on:

- Qualitative composition (including identity of the hydrolysis products of the registered substance) of the test solutions in the *Daphnia* and *Algae* toxicity tests performed as provided in the Registrant's responses to previous draft decisions; and
- Toxic effect concentrations (acute EC50 values) of the hydrolysis products of the registered substance to *Daphnia* and *Algae* predicted by valid (Q)SARs following the requirements of section 1.3 of Annex XI to the REACH Regulation including proper documentation of these estimation methods. In addition the registrant should provide any other available relevant information on the intrinsic properties of the hydrolysis products in an updated dossier.

These newly provided data should be used for the classification and labelling according to Regulation (EC) No 1272/2008 and/or risk assessment of the registered substance.

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:

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu

"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 the 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.

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. 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

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu