~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001516-76-06/F Helsinki, 13 October 2011

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

For [redacted], CAS No 931419-77-1 (EC No 700-067-2), 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], **CAS 931419-77-1 (EC Nr 700-067-2)**, submitted by [redacted] (Registrant), submission number [redacted] tonnes per year.

The compliance check was initiated on 17 September 2010.

On 7 January 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 6 February 2011 the Registrant did not provide any comments on the draft decision to ECHA.

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 amendments 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.

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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.

On 18 August 2011, the Registrant provided comments on the proposals for amendment.

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

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 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) and Annex [redacted] of the REACH Regulation the Registrant shall submit the information using the test method as indicated on

- Water solubility (Annex VII, 7.7.; EU Method A.6.)
- Short-term toxicity testing on invertebrates (preferred species Daphnia EU method C.2) (Annex VII, 9.1.1.)
- Growth inhibition study aquatic plants (preferred algae EU method C.3) (Annex VII, 9.1.2.)

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 **15 October 2012**.

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 13 and with Annexes III and 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.

Missing information related to endpoints

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance [redacted] tonnes per year shall contain [redacted] of the REACH Regulation.

a. For the endpoint on:

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- Water solubility (Annex VII, 7.7.)

The Registrant has provided a QSAR estimate for the registered compound using EPISUITE, showing water solubility between 0.14 and 0.22 mg/L. The Registrant's justification for this is "*Due to the immediate hydrolysis of Aldimine 2 when being in contact with water, a measurement of the water solubility is technically not feasible.*"

According to Annex VII, 7.7 column 2 of the REACH Regulation, the study does not need to be conducted if the substance is hydrolytically unstable at pH 4, 7 and 9 (half life less than 12 hours).This can be shown by undertaking a hydrolysis test (EU C.7. or OECD test guideline 111).

The Registrant provides no quantitative data in the registration dossier to support the claim that the substance is hydrolytically unstable, with a half life of less than 12 hours. In the ecotoxicology section, the Registrant states 'that the impossibility to measure the analytical concentration of the test item may be due to the breakdown of the substance'. This statement indicates that an analytical method was used to detect the substance at certain time points during the duration of the test and perhaps during the preparation of the stock concentration.

In the absence of data in the registration dossier to support the claim that the substance is hydrolytically unstable the adaptation of Annex VII 7.7 column 2 cannot be accepted. Therefore, there is a data gap for this endpoint and the Registrant is accordingly requested to submit the information for water solubility endpoint (Annex VII, 7.7.) on the registered substance.

b. The technical dossier provided testing information on the registered substance on the following endpoints:

    - Short-term toxicity testing on invertebrates (preferred species Daphnia EU method C.2) (Annex VII, 9.1.1.)
    - Growth inhibition study aquatic plants (preferred algae EU method C.3) (Annex VII, 9.1.2.)

The validity of the Algae and Daphnia tests performed is questionable for the reasons set out below:

- The Registrant uses nominal concentrations of the parent compounds, but did not provide evidence that the concentrations of the test substance were maintained to within 80% of the initial concentration throughout the duration of the test. This is a validation criterion according to the Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 adapted to the technical progress by Commission Regulation (EC) No 761/2009, C.3. Algal inhibition test and a recommendation in C.2. Daphnia sp. acute immobilisation test.

- The Registrant indicates that the impossibility to measure the analytical concentration of the test item may be due to the breakdown of the substance, but no further information on the breakdown products has been provided. OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances

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and Mixtures, ENV/JM/MONO (2000)6 and ECHA guidance R7b, table R. 7.8-3 describe aquatic toxicity testing of difficult substances. According to these documents, if the substance is likely to be unstable, a decision to test the parent substance and/or its possibly identified degradation products should be based on a consideration of the half-life of the substance under test and real-world conditions.

- As testing technique, a Water Accommodated Fraction (WAF) was selected due to water solubility of < 1 mg/L. A serial dilution of a single stock WAF was undertaken in both tests over a two day period. According to table R 7.8-3 of ECHA guidance R7b, WAFs should be carefully prepared individually and not by serial dilution of a single stock WAF to ensure to achieve attainment of equilibrium and its compositional stability over time.

- As a testing technique, a Water Accommodated Fraction (WAF) is inappropriate for a substance that is hydrolytically unstable, due to the significant time that is required for test concentration preparation. In the selection of the most appropriate test design, evaluation of the physical chemical properties need to be taken into consideration prior to undertaking the test in order for the test to be valid. ECHA notes that it may be useful to have information on the identity and water solubility of the hydrolysis products. The tests are specified in the method descriptions of C.3. Algal inhibition test and C.2. Daphnia sp. acute immobilisation test of the Commission Regulation (EC) No 440/2008.

The reported two tests for Annex VII 9.1.1. and 9.1.2. endpoints are invalid due to not fulfilling the validation criteria of the test conditions and the reported study design contrary to the legal requirements. Accordingly, the Registrant is required to fill the data gaps for Annex [redacted] - Short-term toxicity testing on invertebrates and Growth inhibition study aquatic plants.

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 the technical progress and use the applicable test methods to generate the information on the endpoints indicated above.

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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,

Jukka Malm
Director of Regulatory Affairs

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