~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001470-84-07/F Helsinki, 24/10/2011

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

For Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride, CAS [redacted] (EC Nr. 440-850-3), 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 **Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride , CAS [redacted] (EC Nr. 440-850-3)** submitted by [redacted] (the "Registrant"), latest submission number [redacted] for 1 - 10 tonnes per year.

The compliance check was initiated on 17 October 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 7 February 2011, ECHA did not receive any comments on the draft decision from the Registrant.

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, the modified draft decision was referred to the Member State Committee.

On 12 August 2011 the Registrant provided comments on the proposals for amendment.

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, a unanimous agreement of the Member State Committee on the modified draft decision was reached on 21 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

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:

- ***The description of the analytical methods or the appropriate bibliographical references for the identification of the substance*** (Annex VI, 2.3.7.).

2) 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 the following information:

- ***Vapour pressure*** (Annex VII, 7.5. Column 2) : Pursuant to the second column of Annex VII adapt the standard information requirement by indicating that the study does not need to be conducted because the melting point is above 300 °C
- ***Partition coefficient n-octanol/water*** (Annex VII, 7.8. Column 2): Provide calculated value for log P as well as details of the calculation method.

3) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 3(29) and Annex VII of the REACH Regulation the registrant shall provide in the IUCLID format a study summary of the following study:

- Annex VII, Section 9.1.1 (IUCLID Section 6.1.3) : study named ***Short-term toxicity to aquatic invertebrates***
- Annex VII, Section 9.1.2 (IUCLID Section 6.1.5) : study named ***Toxicity to aquatic algae and cyanobacteria***

4) Pursuant to Articles 41(1)(a), 41(3), 12(1)(a) and Annex VII of the REACH Regulation, the Registrant shall submit for the registered substance:
    - Any other relevant physicochemical, toxicological and ecotoxicological information that is available

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 24 April 2012 - 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 3, 10, and 12 and with Annexes VI 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.

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 information on the identity of the substance. Annex VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance.

The registration did not contain details of analytical methods to determine all the main constituents which is required by Annex VI, Section 2.3.7. of the REACH Regulation. The substance includes two hydrochlorides per mole of substance and thus HCl is part of the substance identity. Quantitative analytical information for the dihydrochloride was not included in the section 1.4 of the dossier. The registrant is therefore requested to submit the missing quantitative analytical information that enables the HCl to be identified and quantified as required by Annex VI, Section 2.3.7. of the REACH Regulation.

2) Missing information related to endpoints

Pursuant to Article 12(1)(a) of the REACH Regulation, a registration for a substance produced in quantities of 1 - 10 tonnes per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation. The technical dossier provided does not contain valid information for the following endpoints:

- Vapour pressure (Annex VII, 7.5.; EU Method A.4.)
- Partition coefficient n-octanol/water (Annex VII, 7.8., Column 2; Calculation method).

Vapour pressure is a requirement of Annex VII, 7.5 of the REACH Regulation. The data for vapour pressure in the dossier was based on the EU A.4 dynamic measuring method. According to Commission Regulation (EC) No 761/2009 the EU A.4 method for vapour pressure includes eight different measuring methods which have their recommended applicable vapour pressure ranges. A dynamic measuring method is valid to estimate vapour pressure values between 10^3 to 10^5 Pa. The vapour pressure of the registered substance was determined to be 2.3×10^{-9} Pa, which is significantly lower than the range applicable for the method used. The method used to measure vapour pressure in the

registration, EU A.4 dynamic method, is therefore not valid. According to Annex VII, 7.5, Column 2 of the REACH Regulation the vapour pressure study does not need to be conducted if the melting point is above 300°C. The registered substance does not melt up to the decomposition temperature of [redacted]. The Registrant is therefore requested to update the dossier by using the REACH Annex VII, 7.5, Column 2 rules for adaptation of the vapour pressure standard information requirement.

Partition coefficient n-octanol/water is a requirement of Annex VII, 7.8 of the REACH Regulation. It has been reported in the registration dossier that the experimental study for partition coefficient was initiated but it had to be aborted due to technical difficulties. According to Column 2 of Annex VII, 7.8, a calculated value for log Kow as well as details of the calculation method shall be provided in case the test cannot be performed. No calculated value for log Kow has been included in the registration dossier. The registrant is therefore requested to submit a calculated value and the details of the calculation method for log Kow.

3) Lack of study summaries

According to Articles 10(a)(vi) and 111 a technical dossier in the IUCLID format shall include study summaries of all information derived from the application of Annex VII. Article 3(29) defines a study summary as "a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study."

The registrant has not reported in the IUCLID format a study summary within the meaning of Article 3(29) of REACH Regulation for the following studies:

- Short term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1; IUCLID Section 6.1.3).
- Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2 ; IUCLID Section 6.1.5).

In particular, the details of the test conditions (e.g. dissolved oxygen, pH, hardness, temperature), details of the test design (e.g. test medium, test concentrations, number of replicates), observations (mortality in treatments and control), and the results of the analysed concentrations during the test are missing. Under the IUCLID Section 4.23 the registrant has indicated that the test substance is not stable in the medium M4, which is used in a short term toxicity tests on *Daphnia magna*. This gives rise to a serious concern of the validity of the determined endpoint that has been derived from a 48-h static test. Without an appropriate reporting of the test conditions, details of the test design and the results of the analysed concentrations during the test, it is not possible to conclude whether the concern is justified or not and consequently the relevance of the study cannot be assessed. Therefore, the Registrant is required to submit study summaries within the meaning of Article 3(29) of the REACH Regulation.

4) Other relevant physicochemical, toxicological and ecotoxicological information that is available

According to Annex VII of the REACH Regulation any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. The toxicological properties of the substance have been evaluated by the EU Scientific

Committee on Consumer Products (SCCP 2008) and the final report of this evaluation is publicly available. The Registrant is requested to make use of this report and add all relevant data to the registration dossier during the update of the 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:

> "*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 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. 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]

Jukka Malm
Director of Regulatory Affairs