European Chemicals Agency

Helsinki, 17 December 2010

Decision number: CCH-D-0000001297-72-03/F

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

For *4,5-diamino-1-(2-hydroxyethyl)-1H-pyrazole dihydrogensulfate*, CAS 155601-30-2 (EC Nr. 429-300-3), 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 (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 ***4,5-diamino-1-(2-hydroxyethyl)-1H-pyrazole dihydrogensulfate***, CAS 155601-30-2 (EC Nr. 429-300-3) submitted [redacted] (the "Registrant"), latest submission number [redacted] for 1 - 10 tonnes per year.

The compliance check was initiated on 4 May 2010.

The draft decision was sent to the Registrant for comments on 26 August 2010.

By 27 September 2010, ECHA did not receive any comments on the draft decision from the Registrant.

On 29 October 2010 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.

By 29 November 2010 ECHA did not receive any proposals for amendments from the competent authorities of the Member States.

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), 12(1)(a) and Annex VII of the REACH Regulation the Registrant shall submit the information using the test method as indicated on

- Self-ignition temperature (Annex VII, 7.12.; EU Method A.16.)

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 **six 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 does not comply with the requirements of Articles **10, 12 and with Annex VII** of the REACH Regulation. 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.

Pursuant to Articles 10(a)(vi) and 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 contained an adaptation to the standard information requirement for the endpoint on:

- Self-ignition temperature (Annex VII, 7.12.)

The Registrant has waived the study based on Column 2 of Annex VII, 7.12., "test substance has a melting point < 160 °C and is inflammable".

According to Annex VII, 7.12., Column 2, the self ignition temperature test does not need to be provided for a solid substance, if the melting point is ≤ 160 °C. However, based on the study submitted in the IUCLID dossier, section 4.2, the melting point is 175.7 °C. In addition, the non-flammability is not foreseen as an adaptation to the standard information requirement. Therefore, the information requirement for this endpoint is not covered.

The Registrant is accordingly requested to submit the information for this endpoint performed with the registered substance by producing the study in accordance with EU Method A.16, Relative self-ignition temperature for solids.

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 adapted to the technical progress by Commission Regulation (EC) No 761/2009 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]

Executive Director