~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: **CCH-D-0000001091-88-05/F**
Decision date: 2 July 2010

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

For *Acetic acid, chromium salt, basic, CAS 39430-51-8* (EC Nr. 254-447-3), 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 ***Acetic acid, chromium salt, basic, CAS 39430-51-8 (EC Nr. 254-447-3)*** submitted by [redacted] (registrant), latest [redacted] for 1 – 10 tonnes per year.

The compliance check was initiated on 28 August 2009.

ECHA drafted a decision in accordance with Article 41 of REACH. On 16 December 2009, ECHA notified the registrant of its draft decision and invited it to provide comments.

On 15 January 2010, the registrant provided comments on the draft decision to ECHA. ECHA has considered the information received and amended the draft decision accordingly.

On 25 February 2010, ECHA notified the Member State competent authorities of its draft decision and invited them to provide proposals for amendments.

After receiving proposals for amendments from the Member State competent authorities, ECHA did not amend its draft decision and forwarded the proposals for amendments to the registrant on 13 April 2010.

On 12 April 2010, the draft decision was referred to the Member State Committee.

On 20 April 2010 the registrant submitted comments on the proposals for amendments.

The Member State Committee took the comments of the registrant on the proposals for amendments of the Member State competent authorities into account.

After discussion in the Member State Committee meeting of 9-10 June 2010, the draft decision was modified and a unanimous agreement of the Member State Committee on the modified draft decision was reached on 9 June 2010.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

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:
   a. Information on the substance identification and corresponding name and structural formula of the substance as indicated in the comments of the registrant on the draft decision (Annex VI, 2.2.1.).

2) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , Sections 2.3.5., 2.3.6. and 2.3.7. of the REACH Regulation, the Registrant shall provide:
   a. Analytical information to confirm the identity and structure of the registered substance.
   b. Description of the analytical methods used or the appropriate bibliographical references for the identification and quantification of the registered substance. The results of such analysis should also be provided.
   c. The UV/Vis spectrum for the registered substance (Acetic acid, chromium salt, basic).

Pursuant to Article 41(4) of the REACH Regulation the registrant shall submit the information in the form of an updated IUCLID dossier by **6 months after adoption of the decision**.

II. 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 Article 10 and Annex VI thereof regarding the identification of the substance. 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 on the identification of the substance.

In detail:

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.

a. The molecular formula and structural formula indicated in the IUCLID dossier chapters 1.1 and 1.2 do not align with the molecular formula indicated in the submitted spectral information. Therefore, the registrant is requested to submit the correct molecular and structural formula for the registered substance (including the SMILES notation) in accordance with Annex VI, Section 2.2.1. of the REACH Regulation, and the correct molecular weight in accordance with Annex VI, Section 2.2.3. of the REACH Regulation, ensuring that the information is consistent throughout the dossier. The registrant shall update the molecular and structural formula as it was indicated in their comments to this draft decision.

2) Further analytical data

According to Annex VI, Sections 2.3.5. to 2.3.7. of the REACH Regulation, spectral and chromatographic information should be provided that are sufficient to identify the registered substance. The spectral data and analytical information provided by the registrant does not allow the identification of the registered substance for the following reasons:

a. The spectral data and analytical information provided is not sufficient to confirm the quantitative and qualitative composition of the substance acetic acid Cr salt, basic. Therefore, additional analytical information shall be provided to enable the substance to be identified e.g. Atomic Absorption Spectroscopy (AAS) to confirm the presence and quantity of chromium and X-ray diffraction (XRD) to confirm the structure. In addition, a UV/Vis spectrum for the registered substance will be provided as it was indicated in the registrant's comments to the draft decision.
b. The description of the analytical methods or the appropriate bibliographical references for the identification and quantification of the registered substance are missing. This information shall be provided to enable the substance to be identified and quantified. These methods should also include the determination of chromium in the registered substance and results thereof.

III. 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 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.

IV. 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found at the Board of Appeal website 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,

Geert Dancet
Executive Director