~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001698-62-04/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 m-cdea, CAS [redacted] (EC No. 402-130-7), 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 the ECHA has performed a compliance check of the registration dossier for **m-cdea, CAS [redacted] (EC NO. 402-130-7), REGISTRATION NUMBER: [redacted] submitted by [redacted] (Registrant),** latest submission number [redacted] for [redacted]

The compliance check was initiated on 22 December 2010.

On 24 March 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 26 April 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 a proposal for amendment to the draft decision.

On 20 July 2011 ECHA notified the Registrant of the proposal 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 proposal for amendment received and decided not to modify the draft decision.

On 1 August 2011 ECHA referred the draft decision to the Member State Committee.

By 19 August 2011 the registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the 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 from initiating 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:

   a. UV spectral data (Annex VI, 2.3.5.);
   b. A High-pressure liquid chromatogram or a gas chromatogram (Annex VI, 2.3.6); and
   c. A 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), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the test method as indicated:

   a. Granulometry (Annex VII, 7.14.; Method such as OECD Guideline 110)

3) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1) and 111 of the REACH Regulation the Registrant shall submit in the IUCLID format, study summaries of the following studies, provided under the relevant provisions of the REACH Regulation.

   - Skin irritation or skin corrosion (Annex VII, 8.1), IUCLID section 7.3.1.;
   - Eye irritation (Annex VII, 8.2), IUCLID section 7.3.2.;
   - Skin sensitisation (Annex VII, 8.3), IUCLID section 7.4.1.; and
   - Mutagenicity (Annex VII, 8.4), IUCLID section 7.6.1.

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 **13 April 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 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 does not include a UV spectrum. Therefore, the UV spectral data for the registered substance is requested to be submitted according to Annex VI, section 2.3.5. of the REACH Regulation in order to confirm the identity of the substance.

The registration does not include chromatographic data. The composition of the substance cannot be verified in the absence of quantitative chromatographic data. Therefore, chromatographic data, that is a high pressure liquid chromatogram or a gas chromatogram for the registered substance is requested to be submitted according to Annex VI, section 2.3.6. of the REACH Regulation in order to verify the substance composition and confirm the identity of the substance.

The description of the HPLC (high pressure liquid chromatogram) method included for the quantification of substance composition refers to cyanuric acid as the substance. The description of the analytical methods submitted should be consistent with the identities and composition of the constituents listed in section 1.2. Therefore, a description of the analytical methods or the appropriate bibliographic references used for identification of the registered substance is requested to be submitted according to Annex VI, section 2.3.7. of the REACH Regulation.

2) Missing information related to endpoints

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 granulometry data provided in the technical dossier originates from another manufacturing process than that of the registered substance. According to ECHA guidance R.7a page 151 "particle size is not a specific physico-chemical property of a substance. The original size distribution is highly dependent on the industrial processing methods used and can also be affected by subsequent environmental or human transformations. In that respect any published data on particle size will only be pertinent to that particular sample or process."

Therefore, the Registrant is requested to submit manufacturing process specific information to cover the granulometry endpoint for the registered substance using a test method such as OECD guideline 110 or equivalent.

3) Study summaries

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

The Registrant has provided endpoint study records received per inquiry (inquiry number [redacted]) from ECHA. However, in certain cases not all of the information provided to the Registrant has been included in the dossier.
The Registrant has not reported in the IUCLID format, study summaries within the meaning of Article 3(29) of the REACH Regulation for the following studies, provided under the relevant provisions of the REACH Regulation. The missing elements are listed below after each study title.

- Skin irritation or skin corrosion (Annex VII, 8.1, IUCLID section 7.3.1): Applicants' summary and conclusions.
- Eye irritation (Annex VII, 8.2, IUCLID section 7.3.2): Correct test laboratory not indicated.
- Skin Sensitisation (Annex VII, 8.3, IUCLID section 7.4.1): Strain, concentration, no. of animals per dose, interpretation of results.
- Mutagenicity - Ames tests (Annex VII, 8.4, IUCLID section 7.6.1): Strain TA 1538, metabolic activation system, test concentrations, solvent used, observations, interpretation of results.
- Mutagenicity - *In vitro* chromosome aberration (Annex VII, 8.4, IUCLID section 7.6.1): Metabolic activation system, test concentrations, solvent, details on test system & concentrations, observations and interpretation of results.
- Mutagenicity - *In vitro* UDS (Annex VII, 8.4, IUCLID section 7.6.1): Correct test laboratory not indicated, vehicle, fixation time, interpretation of results.

Therefore, the Registrant is requested to provide study summaries of the above studies, including all of the missing elements as listed.

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 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,

Jukka Malm
Director of Regulatory Affairs