



Decision number: CCH-D-0000001576-70-03/F
Decision date: 5 September 2011

Helsinki, 05/09/2011

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

For [REDACTED], 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] submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1 - 10 tonnes per year.

The compliance check was initiated on **9 March 2010**.

On 7 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 6 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This compliance check decision has been targeted to substance identity. ECHA reminds Registrants that a compliance check decision does not prevent the Agency from making a further compliance check of their dossiers at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10 (a)(ii) as well as Annex VI, Sections 2.1, 2.2 and 2.3 of the REACH Regulation the Registrant shall eliminate the following inconsistencies with regard to the information on the identity of the registered substance by application of the IUPAC rules:

- a. In naming the main constituents of the substance the inconsistencies between the provided structural formulae and the IUPAC names of the main constituents shall be eliminated.
- b. The inconsistencies between the provided structural formulae and the IUPAC names of the impurities shall be eliminated.

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 **5 March 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 **Article 10 and with Annex VI** 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.

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 provided information does not allow the registered substance to be unequivocally identified for the following reasons:

- a) Annex VI, Section 2.1.1 of the REACH Regulation provides for the obligation to submit for the registered substance the name(s) in the IUPAC (International Union of Pure and Applied Chemistry) nomenclature. The substance is a multi-constituent substance comprising of two main constituents. The reported name of the substance is not in line with the naming convention for multi-constituent substances and there are inconsistencies between the reported structural formulae and IUPAC names of the main constituents. As a convention, a multi-constituent substance should be named as a reaction mass of the main constituents of the substance. Therefore the terms "main isomer" and "secondary isomer" should not be included in the chemical name of the substance. The name should be based solely on the term "Reaction mass of" and the IUPAC names of the main constituents. Moreover the structural formulae refer to [REDACTED] whereas the

reported IUPAC names refer to [REDACTED]. The Registrant shall eliminate the inconsistencies between the structural formulae and the IUPAC names of the main constituents. The names of the main constituents shall follow the IUPAC rules. Based on the submitted structural formulae, the following IUPAC names and SMILES (Simplified Molecular Input Line Entry Specification) notations of the main constituents appear to be more appropriate than the IUPAC names contained in the technical dossier:

- 1) Constituent 1 with CAS number [REDACTED]:
 - IUPAC name: [REDACTED];
 - SMILES notation: [REDACTED]
- 2) Constituent 2:
 - IUPAC name: [REDACTED];
 - SMILES notation: [REDACTED]

On that basis the multi-constituent substance would appear to be correctly named as [REDACTED].

Structural formulae other than those submitted in the technical dossier would lead to a different multi-constituent substance name.

- b) There are inconsistencies with regard to the provided information on the nature of impurities (Annex VI, Section 2.3.2 of the REACH Regulation), which do not allow deriving a clear impurity profile. The information submitted on the identity of the impurities is not consistent as the reported structural formulae do not correspond to the IUPAC names. The reported structural formulae refer to [REDACTED] whereas the IUPAC names refer to [REDACTED]. The Registrant shall eliminate the inconsistencies between the reported structural formulae and IUPAC names of the impurities. Based on the submitted structural formulae the following IUPAC names appear to be more appropriate than the IUPAC names for the impurities contained in the technical dossier:

- Impurity 1: [REDACTED]
- Impurity 2: [REDACTED]

- Impurity 3:

[REDACTED]

- Impurity 4:

[REDACTED]

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 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,

[REDACTED]

Jukka Malm
Director of Regulatory Affairs