

Decision number: CCH-D-0000002303-86-03/F

Helsinki, 4 July 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Amides, C16-C18 (even numbered), CAS No. N/A (List No. 931-695-7), 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 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for Amides, C16-C18 (even numbered), CAS No. N/A (EC No. 931-695-7) submitted [REDACTED] (Registrant), latest submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 9/12/2011.

On 8 March 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 5 April ECHA received comments from the Registrant to ECHA's draft decision.

ECHA considered the Registrant's comments received and amended the draft decision.

On 25 May 2012 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 of the receipt of the notification.

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 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:

- a. The composition of the substance (Annex VI, 2.3.).

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 **4 September 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 for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 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.

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) Composition of the substance (Annex VI section 2.3. of the REACH Regulation)

ECHA notes that the composition of the substance indicated in the IUCLID dossier, section 1.2, do not align with the chemical representation of what the substance consists of, which is an essential part of substance identification. The concentration ranges for the substance constituents reported are too broad ([REDACTED]) and therefore the registration dossier may cover multiple substances, as follows:

- Stearamide if the typical concentration of the first reported constituent is $\geq 80\%$;
- Palmitamide if the typical concentration of the second reported constituent is $\geq 80\%$;
- Amides, C16-C18 (even numbered) if the typical concentrations of both first and second reported constituent are $< 80\%$.

The Registrant shall revise the reported composition in such a manner that it covers exclusively the substance as identified by the EC entry provided in the dossier: Amides, C16-C18 (even numbered). Therefore reasonable concentration ranges should be reported for all constituents in section 1.2 in such a way that the scenarios when the registration dossier covers mono-constituent substances are excluded.

Regarding how to report the concentration ranges for the constituents of the registered substance, the information shall be included in IUCLID section 1.2.

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.



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