

Decision number: CCH-D-0000003124-85-04/F

Helsinki, 21 May 2013

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Fatty acids, hydrogenated tallow, distn. residues, CAS No 70084-85-4 (EC No 274-307-5), 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 Fatty acids, hydrogenated tallow, distn. residues, CAS No 70084-85-4 (EC No 274-307-5), submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 7.8. of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 8 March 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 27 September 2012.

On 12 December 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 10 January 2013 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. On basis of the comments, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 8 March 2013 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.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision using an appropriate test method:

- partition coefficient n-octanol/water (Annex VII, 7.8.).

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7a, section R.7.1.8.3. (pages 54 to 61, Version of November 2012).

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 **21 January 2014**.

III. Statement of reasons

1) Missing information related to endpoints

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement. The scope of the present decision is the partition coefficient n-octanol/water (Section 7.8. of Annex VII of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1) of the REACH Regulation, any registration for a substance shall contain this information.

The technical dossier contains data for proposed read-across substances for this standard information requirement. According to the information provided by the Registrant the data for these substances stem from a database. As no robust study summary was provided, even for the proposed read-across substances the data neither fulfils the standard information requirement nor the conditions for adapting it in accordance with Section 1.1.1. of Annex XI. As the data is insufficient even for the proposed read-across substances, ECHA does not need to assess whether the read-across adaptation has been justified by the Registrant.

ECHA highlights that if the Registrant sought to build a weight of evidence adaptation for the standard information requirement, he would have had to provide a justification why the data from the studies constitute sufficient weight of evidence for concluding on the partition coefficient n-octanol/water (Section 1.2. of Annex XI of the REACH Regulation).

The Registrant is therefore requested to determine the partition coefficient n-octanol/water using an appropriate test method on the registered substance.

2) Deadline for submitting the information

In the draft decision communicated to the Registrant on 12 December 2012, the time indicated to provide the requested information was 6 months from the date of adoption of the decision. In his comments on the draft decision, the Registrant included a request for an extension of the deadline. The Registrant has indicated that he would need 8 months to carry out the study considering the timelines the testing laboratory is able to offer. He also submitted a letter from a testing laboratory in support of his request. ECHA considers that the request made by the Registrant is adequately justified. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. General requirements for the generation of information

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 or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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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