ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002907-66-03/F Helsinki, 20 August 2013

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

For Fatty acids, C16-18, zinc salts, CAS No 91051-01-3 (EC No 293-049-4), 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, C16-18, zinc salts, CAS No 91051-01-3 (EC No 293-049-4), 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 20 June 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 17 September 2012.

On 21 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 11 January 2013 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 20 June 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)(e), 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.7(a), section R.7.1.8 (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 **20 February 2014**.

III. Statement of reasons

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 does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, but did not provide a sufficient justification. The Registrant has attempted to adapt the standard information requirement utilising the column 2 adaptation which exempts inorganic substances from this requirement stating that the registered substance "is similar to inorganic substances because of its ionic structure". However the registered substance is a salt of an organic acid and not an inorganic substance. Therefore, this column 2 adaptation cannot be applied.

In his comments on the draft decision the Registrant maintained that "*since the substance is similar to inorganic salts because of its ionic structure, waiving in accordance with Annex VII section 7.8 Column 2 of regulation (EC) 1907/2006) is also justified*". The Registrant also states that "*In accordance with section 1, Annex XI of Regulation (EC) No 1907/2006, this study does not need to be conducted for this substance, since it represents an ionic salt of fatty acids with zinc as inorganic cation.*"

ECHA does not consider the nature of the substance, being a zinc salt of a fatty acid as a valid adaptation under REACH Annex XI, section 1 which lays out various conditions under which an adaptation may be applied if testing does not appear scientifically necessary. Furthermore, as stated above, the registered substance is a salt of an organic acid and not an inorganic substance. Therefore, the REACH Annex VII, column 2 adaptation cannot be applied.

ECHA accepts that partition coefficient n-octanol/water information is not relevant for the zinc ion but maintains that the information should be provided for the organic part of the substance and reported in section 4.7. of the IUCLID dossier together with details of its origin and reliability.

The Registrant is therefore requested to submit the information for partition coefficient n-octanol/water (Annex VII, 7.8.) using an appropriate test method on the registered substance.

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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Jukka Malm
Director of Regulatory Affairs