EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288419-34-01/F Helsinki, 27 November 2014

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

For ammonium thiosulphate, CAS No 7783-18-8 (EC No 231-982-0), 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 for ammonium thiosulphate, CAS No 7783-18-8 (EC No 231-982-0) submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex IX, Section 7.16. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted after 12 June 2014, 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 registration at a later stage.

The compliance check was initiated on 6 November 2013.

On 31 March 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 30 April 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 18 July 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014 the Registrant did not provide any comments on the proposal(s) for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 1 September 2014 in a written procedure launched on 21 August 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Dissociation constant (Annex IX, section 7.16.; test method: OECD 112).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **3 June 2015**.

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 dissociation constant standard information requirement (Section 7.16. of Annex IX of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported in quantities of 100 tonnes or more per year per manufacturer shall contain this information.

The technical dossier does not contain relevant data to fulfil this information requirement. ECHA understands that the Registrant sought to adapt the information requirement pursuant to Annex XI, section 1 of the REACH Regulation (test does not appear scientifically necessary), by stating that it is scientifically not possible to perform the test. However, the Registrant did not provide a sufficient justification to explain why it would be scientifically not necessary to perform the test. Indeed, the Registrant just claimed that the substance does not contain relevant functional groups for which an assessment of the dissociation behaviour would provide information for risk assessment purposes and that therefore the determination of a dissociation constant is not considered to be required.

However, ECHA considers that the component ammonium thiosulphate dissociates and that its dissociation constant value might be relevant for the chemical behaviour of the substance in environmentally relevant pH range. Therefore, the Registrant shall provide the dissociation constant value for this component.

As the waiver provided by the Registrant in the dossier with submission number [redacted] is not adequately justified, it cannot be regarded by ECHA as an appropriate adaptation of the standard information requirement.

Therefore, the Registrant is requested to carry out a study on the dissociation constant using the test method, OECD 112: Dissociation Constants in Water, on the registered substance and to submit the resulting information.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and 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 . The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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. 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation