Decision number: CCH-D-2114323440-65-01/F Helsinki, 30 March 2016

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

For tin sulphate, CAS No 7488-55-3 (EC No 231-302-2), 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 tin sulphate, CAS No 7488-55-3 (EC No 231-302-2), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2, Annex VIII, Sections 8.2.1 and 9.1.4 and Annex X, Sections 8.7.2, 9.4.4 and 9.4.6 of the REACH Regulation.

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 21 January 2016 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.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 21 November 2013.

On 19 August 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. That draft decision was based on submission number [redacted].

On 25 September 2014 ECHA received comments from the Registrant on the draft decision.

On 29 September 2015 the Registrant updated his registration dossier with the submission number [redacted].

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

On 21 January 2016 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Composition of the substance (Annex VI, Section 2.3.)
2. Description of the analytical methods (Annex VI, Section 2.3.7.)

B. Information in the technical dossier derived from the application of Annexes VII to XI

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

1. Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species); or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

C. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **9 January 2017.**

Note for consideration by the Registrant
The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a sound scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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 requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Composition of the substance (Annex VI, Section 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain information that is sufficient for establishing the exact composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, ECHA observed that the registered substance is an inorganic mono-constitutent with an indicated typical concentration and concentration range >= [redacted]%. However, the registrant had not provided the purity (and concentration of main constituent) as a range. Moreover, no other constituents or impurities had been listed even though an attached result of analysis ("[redacted]" attached to section 1.4) indicated the presence of two identified impurities, one of which is [redacted], a substance classified as Skin Corr. 1A.

In the updated dossier, the Registrant has now reported the purity as "> [redacted] % (w/w)" and has provided a minimum concentration value for the main consituent concentration as "> [redacted] % (w/w)". The updated dossier now includes one impurity covering a group of constituents "[redacted]" with a upper concentration range of "< [redacted] % (w/w). However, up to [redacted] % of the substance composition remains unaccounted for.

The Registrant is accordingly requested to submit information on the constituent and impurities of the registered substance such that the composition is accounted for to 100 % (w/w). Impurities that are relevant for classification and/or PBT assessment shall be reported independently from their concentration. This information is essential to enable ECHA to have a precise chemical representation of what the substance consists of. The Registrant shall ensure that the information provided on the composition of the substance is consistent with the identity of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report the composition in IUCLID Section 1.2. For each constituent and impurity required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

2. Description of the analytical methods (Annex VI, Section 2.3.7.)

ECHA observes that the Registrant did not provide any appropriate description of the analytical methods used for the identification and quantification of the constituent and impurities required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7. of the REACH Regulation.

ECHA noted that the Registrant only referred to two methods (SM 5030 and SM 5055) not publically available for the quantitative analysis of the substance composition. A description of the methods for sulphate quantification and the free [redacted] content (reported in "[redacted]") was not included.

In the updated dossier, the Registrant has now included descriptions of the methods for SM 5030 and SM 5055. The Registrant has also included quantitative XRF analysis using a standard method DIN 51001 and ICP-OES analysis that gives the hypothetical elemental metal content of the substance. A description of the methods used to quantify the sulphate content (nor the results of this analysis) and the free acid content was not included in the updated dossier.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the sulphate ion. A description of the methods used to quantify the free acid content is required where this impurity is relevant for classification and/or PBT assessment of the substance and required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.
The registrant is requested to include quantitative analysis of the sulphate ion together with a description of the method used. The data should be sufficient to enable the sulphate to be identified and quantified.

As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Effects on terrestrial organisms (Annex X, Section 9.4.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex X, Section 9.4. of the REACH Regulation. Adequate information on effects on long-term toxicity to plants (Annex X, Section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex X, Section 9.4 specifies that long-term toxicity testing shall be proposed by the Registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms.

1. Long-term toxicity testing on terrestrial plants (Annex X, Section 9.4.6.)

The only information provided by the Registrant for this endpoint is a supporting study from the published literature to meet this information requirement, "[redacted]". The study dates from 1940 and is assigned reliability 3 (not reliable) by the Registrant. The study does not follow a test guideline but the method is reported as follows: "Sunflowers, corn, and garden peas were grown in glazed pots, six plants to each pot. Quartz sand was used as the growth medium. The cultures were supplied with nutrient solutions twice daily, and flushed twice weekly with distilled water to prevent accumulation of salts in the sand." The NOEC based on growth is reported as 5 mg/kg soil dw dissolved Sn in the robust study summary.

ECHA notes that key information to judge the reliability of the study is missing. The test duration is not reported and it is not clear whether the plants were grown from seed and therefore emergence as well as growth was assessed. The number of replicates and controls is not reported. There is no information on the lighting regime and intensity, temperature, and volumes of dosing solution added to the plant pots. In addition, only two species (corn and garden peas) were tested with stannous sulphate.

The original study report states that, for pea plants "Concentrations from [redacted] ppm caused toxicity symptoms. These were reduced growth of internodes, reduction in size of roots, reduction in number of roots, absence of flowers in concentrations above [redacted] ppm and yellowing of the lower leaves." It is not clear how the Registrant obtained a NOEC of 5 mg/kg soil dw dissolved Sn from the study given that dosing was via nutrient solutions and no soil concentrations are reported.

Given the data gaps for the study, ECHA judges that it is not of sufficient reliability to be used to fulfil the information requirement. This study does indicate potential toxicity of the substance to terrestrial plants which should be further investigated.

In the comments on the draft decision, the Registrant presents an extensive review of the general behaviour of metals in the environment as well as some information specific to tin (II). It is stated that tin (II) is nearly insoluble in the water column and the majority of tin (II) is precipitated in natural water. The factors influencing behaviour of tin (II) in natural water are discussed (organic matter, pH, ligand, dissolved organic carbon, acid-volatile sulphide, salt content, biomethylation and demethylation). Evidence is presented that tin (II) in the water column binds to particulate matter and partitions to sediment. Evidence is also presented that tin (II) is rapidly oxidised to tin (IV) in sediment and soils and becomes less available to aquatic biota.

The Registrant states that soluble tin (II) will disappear from the water column after a short time period under normal conditions and proposes to conduct stability studies on tin (II) with water, soil and activated sludge under different pH conditions.

ECHA notes that the results of the stability study proposed by the Registrant are not yet available in the registration dossier. Furthermore, it is not clear how the study results would address the information requirement for long-term toxicity testing on terrestrial plants.

The chemical safety assessment does not consider exposure to soil and does not justify why there is no exposure to soil. The Registrant has not derived any PNEC for the soil compartment. The substance has a partitioning coefficient log Kp (solids-water in soil) of 3.28 which suggests a potential to adsorb to soil.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance in the updated dossier and in relation to section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), ECHA considers that the substance would fall into soil hazard category 3. This is because the substance has a log Kp (solids-water in soil) of 3.28 which suggest a potential to adsorb to soil. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only.

There are indications of toxicity of the registered substance to plants. There is one study, of reliability 3, in the registration dossier with a NOEC based on growth reported as 5 mg/kg soil dw dissolved Sn. ECHA therefore considers that the long-term soil toxicity test should be conducted on plants rather than on terrestrial invertebrates.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is required to cover the information requirement. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Terrestrial plants, growth test (test method: OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new studies 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 studies 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 studies 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 studies 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by, Claudio Carlon, Head of Unit, Evaluation, E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.