EUROPEAN CHEMICALS AGENCY

Helsinki, 19 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114359592-42-01/F
Substance name: diiron tris(sulphate)
EC number: 233-072-9
CAS number: 10028-22-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10.12.2014
Registered tonnage band: 1000+T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Name and other identifiers (Annex VI, Section 2.1)**
2. **Nature and order of magnitude of any additives (e.g. stabilising agents or inhibitors);**
3. **Description of the analytical methods (Annex VI, Section 2.3.7);**
   - **Identification and quantification of the main constituent(s)**

You are required to submit the requested information in an updated registration dossier by **28 August 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirement(s) of Annex VI, Section 2 of the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

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.

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Appendix 1: Reasons

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. Name and other identifiers (Annex VI, section 2.1)

According to Annex VI, section 2.3. of the REACH Regulation, the name and other identifiers are required to be reported in a registration dossier such that the substance identity can be verified. Following the principles outlined in chapters 4.1 and 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.4, June 2016), referred hereafter as the "Guidance", a mono-constituent substance is identified by the name and other identifiers (including the molecular and structural formulae) of its main constituent. Furthermore, the information on substance identity reported under the different sections needs to be consistent with one another.

You have reported the name and other identifiers for a well-defined mono-constituent substance identity in section 1.1 of your IUCLID dossier, namely iron(III) sulphate. The name reported in the IUPAC name field, the EC (233-072-9) and CAS (10028-22-5) numerical identifiers, the molecular ($Fe_2(SO4)_3$) and structural information are consistent and refer to iron(III) sulphate. Therefore ECHA understands that the registration dossier refers to the iron (III) sulphate.

However, in the remarks field of the reference substance in section 1.1, you reported the following:

> [...] "*This profile also covers any salts in the form Fe2(OH)x(SO4)(3-0.5x) where x is <1 and where the physicochemical properties and hazard profile do not differ from those of Fe2(SO4)3.*" [...]

This information reported in the remarks field refers to iron hydroxysulphates. However iron hydroxysulphates have different substance identities (different molecular and structural formulae, different name and numerical identifiers) and therefore cannot be covered by the same registration as iron(III) sulphate.

You are therefore requested to remove the text referring to iron hydroxysulphates from the remarks field. You shall also ensure that the compositional information reported in section 1.2 and the analytical data reported in section 1.4 are consistent and refer to iron(III) sulphate.

Note that in case you intend to register e.g. iron hydroxysulphates, you should consider your obligations under REACH, in particular the principles of substance identification as explained in the Guidance.

In your comments to the draft decision, you stated that the registered substance is solely diiron triuslfate and your agreement to remove the text above from section 1.1 in an updated dossier to comply with this request.

2. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors) (Annex VI, Section 2.3.4.)

The definition of substance as per Art 3(1) of the REACH Regulation states that a substance includes "any additive necessary to preserve its stability". Following the principles outlined in section 2.2 of the Guidance, the role of an additive is therefore solely to ensure the stability of the manufactured substance; i.e. without it, the substance would be transformed to one with a different identity. Additives with any function other than stabilization cannot be reported in the compositional information.

You have reported two composition records in section 1.2 of your dossier [redacted] and "[redacted])". Each composition record reports "sulfuric acid" as an additive in its Additives section with the function "stabilizer" selected from the available options in the picklist for reporting additive function. No supporting documentation to demonstate the necessity of sulfuric acid for the stability of iron(III) sulphate was included in your dossier.

It is not self-evident that a stabiliser would be necessary for iron(III) sulphateas iron (III) sulphate is commercially available without stabilisers. You have not included supporting documentation to demonstrate that sulfuric acid is required for stability of iron (III) sulphate.
Consequently, the reported stabilizer role of sulfuric acid required clarification and revision as appropriate.

You are therefore requested to either (1) remove sulfuric acid from the additive section of the composition records in section 1.2 or (2) include supporting documentation that demonstrates that sulfuric acid is required for the stability of iron(III) sulphate. If the sulfuric acid is an impurity resulting from the manufacturing process, it shall be reported as an impurity in each composition record.

Technical instructions on how to comply with the request are given below:

- (1) Sulfuric acid does not have stabilising role: remove sulfuric acid from the additives block of each composition record. Where sulfuric acid is an impurity resulting from the manufacturing process, it shall be reported in the impurities block.
- (2) Sulfuric acid has a demonstrable stabilising role: include a supporting scientific justification with supporting citations from scientific literature, if available. This documentation can be included as an attachment in section 1.4.

In your comments to the draft decision, you clarified that sulfuric acid is an impurity from the manufacturing process and that you will report it in the impurity section of the composition record in an updated dossier to comply with this request.

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

According to Annex VI, section 2.3.7 of the REACH Regulation, a registration dossier shall report a description of the analytical methods or the appropriate bibliographic references for the identification of the substance and where appropriate for the identification of impurities and additives. The reporting shall be given in sufficient detail that the methods may be reproduced.

The quantitative analyses reported in "[redacted]" give the elemental analysis on a representative iron (III) sulphate. The data reported was obtained on an aqueous solution of iron (III) sulfate. XRD data referring to iron (III) sulfate was not included. The XRD data that was included refers to substances with different identities (Fe14O3SO4 63.H2O, Fe4(SO4)6.15H2O). Analytical data included in the report "[redacted]" also refers to substances with different identities, namely various iron hydroxysulfates and iron (II) sulfate.

The data submitted does not enable the identity or compositional information of iron (III) sulphate to be verified as XRD data or equivalent information has not been reported. The analytical data included in section 1.4 is therefore insufficient for the verification of the iron(III) sulphate identity and compositional information reported in sections 1.1 and 1.2 of your dossier.

You are therefore requested to include XRD data or suitable alternative data that can provide the same information (e.g. a record that enables the characterisation of the atomic structure of the substance, showing for the match of the identified absorption bands or emission wavelengths of a sample of your iron sulphate vs. that of a certified standard reference). The data reported is required to be sufficient for the verification of the subtance identity.You may use any method and/or combination of methods to do this. You shall include a description of each method used in such detail that the method may be reproduced.

Technical instructions on how to report the requested information:

- The documentation shall be attached to section 1.4 of your dossier.

In your comments to the draft decision, you clarified that analytical data for other substances were included in section 1.4 and that these were not intended to be taken into account for this registration. You outlined that XRD data for diiron trisulfate had been reported but that it was not clearly stated which diffractograms was relevant for this registration. You stated your commitment to providing this clarification in an updated dossier. You included a copy of a certificate of analysis and stated that a CEN standard was used to obtain the data. You outlined that the text of the standard cannot be included due to copyright issues. You stated your commitment to include the data and clarification in an updated dossier to comply with the request for a description of the methods used to quantify the composition of diiron trisulfate. You also clarified that diiron trisulfate in aqueous solution always has an iron hydroxysulfate impurity and that the calculated molecular formula is from both the impurity and main constituent. Provided the molecular formula of the main constituent is consistently reported as "Fe2(SO4)3)" in all documentation reported in section 1.4, this will clarify that hydroxysulfate is an impurity.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 27 November 2015.

For final decision: The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

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

3. 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 your Member State.