ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005156-76-02/F Helsinki, 28 August 2014

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

For Slags, ferromolybdenum-manufg., silicothermic, CAS No 84144-95-6 (EC No 282-217-2), 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 Slags, ferromolybdenum-manufg., silicothermic, CAS No 84144-95-6 (EC No 282-217-2), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 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 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 31 May 2013.

On 5 November 2013 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 27 November 2013 ECHA received comments from the Registrant on the draft decision.

On 17 December 2013 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

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.

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. Name or other identifier of the substance (Annex VI, 2.1.), as further specified under section III.A.1. below;

2. Composition of the substance (Annex VI, 2.3), as further specified under section III.A.2. below;

3. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as further specified under section III.A.3. below.

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 **5 December 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 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. Name or other identifier of the substance (Annex VI, 2.1.),

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the cornerstone of all the REACH obligations.

ECHA notes that the Registrant has not provided appropriate identifiers for the registered substance, as required according to Annex VI Section 2.1. of the REACH Regulation.

More specifically, ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances such as the registered substance shall consist of two parts: (i) the chemical name and (ii) a more detailed description of the manufacturing

process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance, as explained below.

The Registrant described in Section 3.1 of the IUCLID dossier the starting materials of the substance as follows: "*The main source of molybdenum oxide for this manufacturing process is roasted molybdenite concentrate (EINECS 289-178-0/CAS 86089-09-0), but other molybdenum-bearing materials such as calcium molybdate may be also used. The roasted molybdenite concentrate has a grain size 0/4 mm and contains impurities such as Al, Si and Fe.*" whereas the EC inventory describes the substance as "*Product of silicothermic reduction of molybdic oxide*". However, the Registrant has not described the variability in the identities and compositions of the starting materials, in particular the "*other Molybdenum bearing*" source materials are not fully defined and the impact of using such source material on the substance composition is not explained.. As the composition of the starting material is one of the factors determining the composition of the registered substance, the identities and compositional information of all individual starting materials (in terms of identities and concentration ranges of constituents) are necessary elements for the identification of the registered substance itself. According to section 4.3 of the Guidance, for UVCB substances such as the registered substance any significant change of source or process would be likely to lead to a different substance that should be registered again.

Other elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. In particular, the ratio of reactants used and specifications of any other manufacturing process parameters, such as temperature, pressure, cooling parameters, have not been indicated in sufficient detail. Furthermore, the Registrant indicates that [redacted] ECHA notes that the use of aluminium powder as reducing agent and its impact on the substance composition is not fully explained. It is not clear whether aluminium powder can be used as the major/sole reducing agent. The EC entry provided for the registered substance refers to a silicothermic process only.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered UVCB substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation the Registrant shall correct and complete the manufacturing process description. This information shall include:

- Identities of the starting materials, and
- Compositional information of the starting materials, and
- Ratio of reactants, and
- Specifications of the process parameters, including temperature, pressure, cooling parameters and any other process steps and parameters which are necessary to obtain the registered substance and which may affect the substance composition.

In addition, it shall be described how the variability in the source and the manufacturing process parameters affects the substance composition.

ECHA recognises that the Registrant may cover different grades in a registration based on different sources and/or manufacturing processes. In these cases, the Registrant shall

provide the required information on the source, manufacturing and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration.

As for the reporting of the information in IUCLID, the chemical name and the manufacturing process description should be specified in the "IUPAC name" and "Description" fields, respectively, in IUCLID section 1.1.

2. 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 sufficient and appropriate information for establishing the composition of the registered UVCB substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, the compositional information in IUCLID section 1.2 does not correspond fully with the analytical information provided in IUCLID section 1.4. [redacted] Similarly, the concentration ranges provided for Oxygen ([redacted]) and Magnesium ([redacted]) do not match the values recorded in the elemental analysis ([redacted] respectively) in IUCLID secion 1.4. Additionally, there is no concentration range provided for the constiuent Cristobalite.

ECHA therefore concludes that the identity and quantity of the constituents/groups of constituents has not been correctly reported in the composition.

For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide the missing information on the composition of the registered substance, for ECHA to have a precise chemical representation of what the substance consists of. The concentration range values must be representative for the registered substance as manufactured and it shall be clarified how the minimum and maximum values for each group of constituents were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA is not able to conclude on the representativeness of these values.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2. For each constituent 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. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents e.g. "silicon dioxide equivalent",

generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 on the ECHA website.

Where the Registrant covers different grades in a registration based on different constituents, the Registrant shall report separately the source, manufacturing process and the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

The Registrant shall ensure that the information provided in section 1.2 shall be consistent with both the crystalline compositions and the elemental compositions reported in section 1.4.

3. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7)

"Description of the analytical methods or the appropriate bibliographical references for the identification of the substance" is a standard information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided elemental analysis results on the substance. However, the results on the elemental composition only account for ca. [redacted]% with a remark "Balance aluminum + silicon + iron = [redacted] %" (Attachment "XRD slag melt 1237.xls"); the individual elemental contents of aluminum, silicon and iron are not included in the dossier. According to the information the Registrant provided on the starting materials, these elements would be expected to be predominant elements in the substance. Without information on their individual contents the identity and composition of the substance cannot be verified.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a description of the analytical methods or the appropriate bibliographical references, as well as the results from these analyses, for the identification and quantification of all elements present in the substance, and of the actual constituents that can be identified, giving the results separately for each element/constituent. The descriptions should be given in such detail that the method can be reproduced. Such information should include a detailed experimental protocol, any calculations used as well as the results of the analyses.

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

IV. 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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