EUROPEAN CHEMICALS AGENCY

Helsinki, 5 April 2016

Addressee: [redacted]

Decision number: CCH-D-2114321258-54-01/F
Substance name: Reaction mass of ditungsten carbide and tungsten carbide
EC number: 915-093-1
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 12.01.2015
Registered tonnage band: 10-100T

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. **Composition of the substance (Annex VI, section 2.3): Information which is suitable and necessary to allow ECHA to establish and verify the composition and the identity of the registered substance;**

2. **The description of the analytical methods (Annex VI, section 2.3.7.)**

You 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 scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **12 July 2016. 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

[For the final decision: 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 Guilhem de Seze, Head of Unit, Evaluation E1

[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.

Appendix 1: Reasons

Pursuant to Article 10(a)(ii) of the REACH Regulation, your technical dossier registered at 10-100 Tonnes per year 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 cornerstone of all the REACH obligations.

ECHA notes that you have not included sufficient information on the composition of the substance to enable the identity of the registered substance to be verified, as required under Annex VI, Section 2.3. of the REACH Regulation.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity. In that respect, according to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and

- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.

- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

Furthermore, in accordance with section 4.2 of the Guidance, the composition of a well-defined substance shall normally be described up to 100%, and each constituent requires a complete chemical specification, including structural information. The composition shall represent the registered substance as it is manufactured, as indicated in section 8.1.2 of the Guidance.

In the present dossier, you identified the registered substance as a well-defined multi-constituent substance with the IUPAC name "Reaction mass of ditungsten carbide and tungsten carbide". In section 1.2 of the dossier two main constituents are listed; [redacted] with broad concentration ranges [redacted]% w/w reported for both constituents. You included also groups of impurities identified as "Trace impurities" in the composition with the remark: "Total impurities less than [redacted]%, no single impurity greater than [redacted]% is considered relevant for classification."

ECHA notes that no structural formula is provided in section 1.2 for [redacted], however in section 1.1 in the structural formula field you state that the substance refers to [redacted]

ECHA notes further that from the phase diagram for tungsten carbides available in literature it is not expected that concentration ranges of W2C+WC system would vary significantly. The same [redacted]% w/w ranges are specified in Table 2 "Sameness description for [redacted]" provided in the attachment "[redacted]" included in section 1.4.

Therefore the provided broad concentration range [redacted]% does not seem to be representative for the substance as it is manufactured /imported by you, but rather depict the criteria used to determine the substance sameness at the level of a SIEF.

In addition, the composition of the registered substance (including concentrations of the main constituents) and the identity of the constituents cannot be verified by the analytical information included in section 1.4, as explained in more detail below (see section 2).

ECHA therefore concludes that the compositional information has not been provided to the required level of detail for the verification of the composition as registered by his legal entity.

You are accordingly requested to revise the compositional information providing the structural information of ditungsten carbide and representative concentration ranges for both of the two main constituents. The concentration range values reported must be representative for the composition of the substance registered by this legal entity and include a clarification on how the minimum and maximum values for each constituent were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.).

Regarding how to report the composition of the registered substance in IUCLID, the following applies:

- You must report individually each main constituent and specify IUPAC name, CAS number, EC number, molecular and structural formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

- You must also report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

- Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

Where you cover different compositional grades of the same substance in a registration dossier, you must report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different grades, then these must be presented separately. Instructions on how to report multiple compositions are available in the "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" available on the ECHA website at http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-manuals.

You must ensure that the composition is verifiable and therefore is supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as indicated below (see section 2).

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

ECHA notes that you have not provided sufficient information on the methods used to determine the identity and composition of the substance registered by your legal entity, as required by Annex VI, Section 2.3.7. of the REACH Regulation.

Annex VI, section 2.3.7 of the REACH Regulation requires that each registration dossier contains a sufficiently detailed description of the analytical method used for establishing the composition of the registered substance and therefore its identity. This information shall be sufficient to allow the method to be reproduced.

ECHA observes that you did not attach any spectral or analytical data that could support the identity and composition of the registered substance. In section 1.4 of the dossier, a certificate of analysis including results of an elemental analysis and some physical parameters is attached ("[redacted]"). However, there is no corresponding description of the methods that were used to generate these results. Furthermore, references to different analytical methods available for identification and quantification of the registered substance are mentioned in the attachment "[redacted]" (i.e. the methods [redacted]) and also in the "Analytical methods and spectral data" field in IUCLID section 1.4 ("[redacted]"). However no corresponding spectral or analytical data that could support the identity of the registered substance and its constituents ([redacted]) and potential impurities have been provided in the dossier.

ECHA therefore concludes that you did not provide an appropriate description of the analytical methods used to derive the composition as reported in IUCLID section 1.2. You are accordingly requested to provide a sufficient description of the analytical methods used for the identification and quantification of the constituents contributing to the composition and the identity of the registered substance. The descriptions 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. For inorganic solid substances, as the registered substance, a combination of XRD techniques and elemental analysis are considered as appropriate methods to identify and quantify the substance, as explained in chapter 7.5 of the Guidance.

The analytical data provided on the identification and quantification of the substance shall be consistent with the composition and identity reported for the substance. Where the revised identification and/or compositional data is not consistent with the reported composition and/or identity of the substance, you must accordingly correct the information provided on the composition of the registered substance and on the identifiers of the substance in IUCLID sections 1.2 and 1.1 (respectively).

As for the reporting of the information in IUCLID: The spectral data and description of the methods used shall be attached in IUCLID section 1.4.

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 16 July 2015.

ECHA notified you of the draft decision and invited you to provide comments. ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).

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

2. 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.

3. In relation to the information required by the present decision, the sample of the substance used to determine composition of the substance must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported 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 If the registration of the substance by any registrant covers different grades, the sample used to determine composition of the substance 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 test(s) to be assessed.