EUROPEAN CHEMICALS AGENCY

Helsinki, 15 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350387-46-01/F
Substance name: orthoboric acid, potassium salt
EC number: 244-038-8
CAS number: 20786-60-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27 May 2013
Registered tonnage band: 100-1000T

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 or other identifier (Annex VI, Section 2.1.) of the registered substance;**
   - **Chemical identifiers**
   - **Manufacturing process**

2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Identity of the constituents**

3. **Spectral data (Annex VI, Section 2.3.5);**

4. **Description of the analytical methods (Annex VI, Section 2.3.7);**
   - **Identification and quantification of the constituents**
   - **Identification and quantification of the counter-ion**

You are required to submit the requested information in an updated registration dossier by **22 March 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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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, 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, Section 2.1.)

ECHA notes that you identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).
According to Annex VI, Section 2.1. of the REACH Regulation, the naming of UVCB substances shall consist of two parts: (a) the chemical name and (b) 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: 1.4, June 2016) – referred to as the "SID Guidance" thereinafter.

a) Chemical identifiers

You have identified the registered UVCB substance with EC nr.: 244-038-8 (Orthoboric acid, potassium salt) and CAS nr.: 20786-60-1 (Boric acid (H3BO3), potassium salt (1:?)). You also indicate that: "[redacted]".

The EC and CAS identifiers provided may cover several substances, while the additional description provided ("numerous potentially oligomeric poly borate salts") does not allow to determine more precisely the identity of the substance that is actually covered.

In other words, the EC and CAS entries appear to refer to an unspecified potassium salt of boric acid that may not be representative for the registered substance. Therefore, these EC and CAS entries appear to be too broad to sufficiently identify that substance.

b) Manufacturing process

In section 3.1, you describe the manufacturing process as follows: "[redacted] However no information on the degree of neutralisation ([redacted]) is provided in the dossier. Furthermore it is stated that: "[redacted]."

Furthermore, the identity and function of the "[redacted]" as well as of the two other components "[redacted]" and "[redacted]" are not further described.

However, it is not clear from the description whether the manufacturing process of the registered substance finishes after the neutralization step. It is also unclear whether the abovementioned reagents ("[redacted]") (1) react with the starting materials or an intermediate, and/or (2) are constituents of the registered substance, e.g. if their function is an additive and necessary to preserve the stability of the registered substance.

As a consequence, additional information on the starting materials, the reagents and steps following the neutralisation steps appears to be necessary to determine all the steps of the manufacturing process, which is part of the name of the registered substance, and to fully identify the registered substance.

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

As a consequence, the identity of the registered substance remains unclear and there is a data gap.

Therefore, to address sections a) and b) above, you shall provide a detailed description of the manufacturing process including:

- Identity of the starting materials and the function of any other components used to manufacture the registered substance (e.g. [redacted]);
- Ratio of the starting materials used (including [redacted], and all the other reagents used in the manufacturing process, i.e. [redacted]);
- Description of all steps of the manufacturing process applied, including neutralization and purification steps;
- Any further relevant operating parameters (e.g. temperature, pressure).

You shall ensure that the chemical name, the identifiers (such as EC and CAS entries) and manufacturing process description are representative of the substance registered and consistent with each other.

If other components used to manufacture the registered substance (e.g. [redacted]) are present in the substance and cannot be removed without affecting the stability of the substance itself, they shall be included in the substance composition.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the "Description of composition" field in IUCLID section 1.2.

If the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 244-038-8 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

Further technical details on how to identify your substance in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" (version 1.0, April 2016) on the ECHA website.

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

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

In that respect, according to chapter 4.3 of the SID Guidance, you should note that for UVCB substances the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature; and
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In section 1.2 of the IUCLID dossier you have reported the composition as consisting of [redacted]% of the substance itself, i.e. "[redacted]" but stating that it contains "[redacted]". No information on the identity and concentration levels of these constituents or groups of constituents is reflected in the compositional information.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

You are accordingly requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of.

Further subdivision of the substance is therefore needed which means qualitative and quantitative compositional information of the constituent(s) i.e. breakdown of the composition shall be included in the dossier.

Constituents can also be grouped based on chemical similarities and/or degree of oligomerisation. The composition shall be supported by the relevant analytical data in section 1.4. If it is not possible to derive the composition based on analytics, "hypothetical" composition based on the knowledge of the reaction, ratio of reactants, expected products, etc. can also be provided alternatively. In such case, a scientifically valid justification shall be provided.

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

You 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, generic molecular and generic structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

You shall ensure that the reported composition is consistent with the description of the process used for the manufacturing of the registered substance, including the identity of the starting materials used. You shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" (version 1.0, April 2016) on the ECHA website.

3. Spectral data (Annex VI, Section 2.3.5.)

Spectral data are a formal information requirement of Annex VI Section 2.3.5.

No spectral data have been provided in IUCLID section 1.4 of the registration dossier. In section 1.4, it is stated " *The description of the analytical methods and spectral data are included below. It is not possible to isolate orthoboric acid, potassium salt from the chemical matrix in which it is made.*"
Contrary to the statement in the registration dossier, no analytical data are provided. Furthermore, ECHA notes that, whether or not the registered substance may be isolated, analytical methods (e.g. ^{11}B-NMR, XRD, IR, MS) are available to identify it.

Therefore, appropriate spectral data can be provided but, in the absence of such data, the identity of the substance cannot be verified and there is a data gap.

Accordingly, you are requested to provide spectral data that would confirm the identity of the registered substance (e.g. ^{11}B-NMR, XRD, IR, MS).

As for the reporting of the spectral data in the registration dossier, the information shall be included in IUCLID section 1.4. You shall ensure that the description of the analytical methods used for the recording of the spectra is specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

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

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 notes that the description of the analytical methods that would allow the identification and quantification of the substance including its constituents is missing from the dossier. In section 1.4 it is stated "*The description of the analytical methods and spectral data are included below. It is not possible to isolate orthoboric acid, potassium salt from the chemical matrix in which it is made.*" Moreover, no information on the identification and quantification of the counter-ion (potassium ion) has been provided in the dossier.

Contrary to the statement in the registration dossier, no description of the analytical methods is provided. Furthermore, ECHA notes that, whether or not the registered substance may be isolated, analytical methods (e.g. ^{11}B-NMR, XRD, IR, MS) are available to identify it.

ECHA therefore concludes that the description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance is missing from the dossier. You shall provide the description and results of qualitative and quantitative analytical methods (or alternative methods/techniques, see above) used to verify the identity of the registered substance and its constituents/groups of constituents required to be reported in section 1.2.

Furthermore, you shall also provide information on the identification and quantification of the counter-ion. When a direct analysis is not possible, other alternative analytical methods may be applied (including methods based on the derivatization or using model systems) to analyse 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.

In case when the composition can only be derived based on theoretical assumptions or calculations, all information that is necessary to understand how the composition has been established needs also to be provided in section 1.4.

As for the reporting of the data in the registration dossier, the information should be attached in section 1.4 of the IUCLID dossier. You shall ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results obtained.

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 12 August 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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 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. 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.