EUROPEAN CHEMICALS AGENCY

Helsinki, 15 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114347683-43-01/F
Substance name: Potassium difluorodihydroxyborate(1-)
EC number: 286-925-2
CAS number: 85392-66-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 16 March 2016
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(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.) of the registered substance;**
   - **Chemical Name**
   - **EC and/or CAS entry**
   - **Manufacturing process**

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

3. **Description of the analytical methods (Annex VI, Section 2.3.7.) on the registered substance;**
   - **Identification and quantification of the constituents**

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.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are, therefore, essential parts of substance identification. ECHA notes that you have not provided appropriate identifiers for the registered substance, as required according to Annex VI Section 2.1. of the REACH Regulation.

More specifically, in line with the ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH and CLP (June 2016 Version 1.4), for UVCB substances, the main identifiers are related to the source of the substance and the specific manufacturing process used. The naming of UVCB substances shall consist of two parts: the chemical name and a more detailed description of the manufacturing process.

ECHA notes that you identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). In the description field of the reference substance general information, you reported that the subtance is a: "[redacted]".

However, the name and other identifiers reported for your substance (including EC, CAS and IUPAC identifiers and also the molecular and structural information) are specific for the well-defined substance "potassium difluorodihydroxyborate(1-)".

In addition, the description of the manufacturing process you have reported in the description field of the reference substance in section 1.1 only refers to "[redacted]". You have provided minimal additional information in section 3.1: "[redacted]"
However, no further details on the starting materials used, on their ratio and on the process were reported in your dossier. Furthermore, conditions specific for the manufacturing process of the registered substance were not reported in the dossier and details on the collection and purification steps were not provided.

Based on the above, the name and other identifiers provided in the dossier do not allow to identify the substance in an unambiguous manner. Firstly, the identifiers (including EC, CAS and IUPAC identifiers and also the molecular and structural information) are specific to a well-defined substance and are therefore not representative of the substance registered as a UVCB. Secondly, the very basic description of the manufacturing process reported is overly generic and applicable for multiple processes and therefore not sufficient to identify a UVCB substance.

In accordance with Annex VI (2.1), you are requested to revise the name and other identifiers such that they refer unambigously and consistenly to your substance. You shall report a chemical name that is representative of your UVCB substance (e.g. based on source and process as appropriate).

Concerning the identifiers, you are requested to remove the CAS and IUPAC identifiers and also the molecular and structural information and to report the identifiers appropriate to the UVCB substance, if available. The EC entry shall also require revision but it is not technically possible to do this at this stage in the decision making process. You are requested to follow the technical instructions outlined below.

Concerning the description of the manufacturing process you are requested to submit sufficiently detailed information to allow ECHA to verify the starting materials that are used, and how any other steps and process parameters may affect the compositional profile of the substance and therefore its identity. The description shall include as appropriate:

- The identities and ratios of the starting materials
- A description of the manufacturing process and any relevant steps in the process including specific parameters relevant to each manufactured compositions covered by this registration.

Regarding how to report the requested information in the IUCLID dossier, the following applies as appropriate:

- The revised chemical name shall be reported in the IUPAC name field. Appropriate molecular and structural information will be reported in their respective IUCLID fields in section 1.1.

- The description of the manufacturing process shall be included in the description of the substance field in section 1.1.

- An appropriate CAS entry shall be reported in the CAS entry field if available. The current CAS entry (i.e. 85392-66-1) does not identify the registered substance, may reported under the "related CAS information" field in IUCLID section 1.1.

- You shall note that the registration is currently linked to EC number 286-925-2 referring to Potassium difluorodihydroxyborate(1-). In case 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 286-925-2 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 information on how to report the description of the manufacturing process is available in "Data Submission Manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" published on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

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 cornerstone of all the REACH obligations.

More specifically, according to chapter 4.3 of the Guidance, 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. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance.

The composition shall be reported to represent 100 % of the substance. The concentration values for each chemical constituent shall be representative for the manufactured substance. For each constituent and group of constituents, the typical lower and upper concentration level shall be indicated.

You have reported an hypothetical elemental composition by the elemental analysis data and this hypothetical elemental composition only accounts for up to [redacted] % of the substance based on the reported concentation ranges.

In addition, the reported composition does not contain compounds of K, B, OH and F identified from the information provided in section 1.4 (e.g. [redacted]) in consistence with the information reported in the description field in section 1.1.: "[redacted]."

You have reported, for each of the hypothetical constituents, the following in the remarks fields: "[redacted]"

Moreover, sets of analytical data submitted in section 1.4 (labelled as referring to "powder", "paste h", "paste h 80", "paste hc" grades) report significantly different compositions.

Based on the reported composition does not represent 100 % of the substance. In addition, the chemical speciation submitted in section 1.4, describing the constituents of the substance composition, must be reflected in the composition reported in section 1.2 of the dossier. Finally, the various compositions that result from the sets of analytical data submitted in section 1.4 are not reported specifically in section 1.2.

In accordance with Annex VI (2.3), you are therefore requested to report the chemical composition of your substance in terms of its chemical constituents. More specifically, you are required to report separately all the different compositions of the registered substance and to ensure that for each composition, the constituents reported represent 100 % of the composition. In that respect you must specify:

- 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. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance.

The concentration values for each chemical constituent shall be representative for the manufactured substance. For each constituent and group of constituents, the typical lower and upper concentration level shall be indicated. The hypothetical elemental composition may be reported in section 1.2 as complimentary information but cannot preclude information on chemical composition.

Note that where the identities of some chemical constituents are not precisely known, these constituents may be represented and quantified as groups of constituents. This does not preclude you from the requirement to report representative information on the overall composition of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: you shall indicate the composition of the registered substance in IUCLID Section 1.2. For each chemical 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 constituents that you report under a generic description, a generic chemical name describing the group of constituents, 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.

You shall ensure that your dossier includes the necessary analytical information as required under Annex VI section 2.3.7 to verify the reported composition(s).

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

Pursuant to Annex VI, Section 2.3.7. the description of the analytical methods used for the identification and quantification of the constituents has to be reported.

You indicated in the description field in section 1.1 of the IUCLID dossier that the registered substance typically consists of complex [redacted] based constituents. However, the data included in section 1.4 of the dossier identifies only a very limited number of constituents and no quantitative data was provided in the dossier. Specifically, you have included elemental analysis, NMR spectra and qualitative XRD patterns obtained for different chemical compositions of the registered substance ("powder", "paste h", "paste h 80", "paste hc").

In addition, the provided diffraction patterns clearly indicate the presence of unreported constituents. The XRD spectra do not report the quantification of these constituents.

Based on the above, the analytical information reported (description of the methods used and the corresponding data), as quantitative data related to the actual costituents (not reported in the composition in section 1.2) of the substance are missing, is not sufficient to establish the identity and quantification of specific constituents and/or group of constituents that contribute to the substance composition(s) of the registered substance
In accordance with Annex VI, Section 2.3.7., you are requested to submit the description of the analytical method(s) used for the quantification of the chemical constituents of the registered substance, that are sufficient to verify the composition(s) and in turn the identity of the registered substance. The description(s) 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 results of quantitative analysis shall be recorded on the substance registered and shall cover the composition(s) registered.

Note that this requirement is that the information submitted is sufficient to enable the substance to be identified in Section 1.1 of the dossier and all the respective compositions reported in Section 1.2 to be verified. Consequently, you may use any method or combination of methods to fulfil this requirement (e.g. elemental analyis, quantitative XRD, XRF, NMR, TGA etc).

As for the reporting of the above data in the registration dossier, the information, including any a scientific justification for not including the full set of data, should 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 19 February 2016.

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

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. 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.