EUROPEAN CHEMICALS AGENCY

Helsinki, 29 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114360551-55-01/F
Substance name: Aluminum potassium fluoride
EC number: 262-153-1
CAS number: 60304-36-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27.09.2012

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 registered substance (Annex VI, Section 2.3.);**
   - Concentration values
   - Identity of the main constituent(s)
2. **IUPAC name (Annex VI, Section 2.1.1);**

You are required to submit the requested information in an updated registration dossier by **5 September 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. Composition of the substance (Annex VI, Section 2.3.)

1.1 Concentration values

Annex VI, section 2.3. of the REACH Regulation requires that information given on composition of each substance is sufficient to enable each substance to be identified. Section 4.2.2 of the Guidance on the identification and naming of substances under REACH and CLP (Version: 1.4, June 2016), hereafter referred as "SID Guidance", defines a multi-constituent substance as a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w).

You have reported in section 1.2 of your dossier three constituents contributing to the substance composition; namely [redacted]. The concentration range reported for these constituents are [redacted], [redacted] and [redacted] %(w/w), respectively.

Compositions where a main constituent is not present (i.e. the concentration of a reported constituent is 0 %) are considered as different substance identities under REACH. As specified in the SID Guidance, all main constituents of a multi-constituent substance need to be present in the substance at the concentration between 10 and 80 % (w/w). The composition reported in section 1.2 of your dossier does not fulfil these requirements.

We note that you have included the following statement in the remarks field for the constituent [redacted] "*This main constituent has a typical concentration lower than* [redacted] *but this substance can be shown to have similar physico-chemical properties, the same Hazard profile and similar use and exposure scenarios as the substances with the same identity with a typical concentration* [redacted] *for this main constituent*". For this constituent, the typical concentration is reported to be < [redacted] % (w/w) and the concentration range to be [redacted] %(w/w). This kind of derogation is, however, allowed neither by the REACH regulation nor by the SID Guidance for the multi-constituent substances.

In accordance with Annex VI section 2.3, you are requested to revise the composition reported in section 1.2 of the IUCLID dossier such that the constituent concentration ranges refer to a multi-constituent substance identity with concentration ranges of the main constituents between 10 and 80 %. This composition reported shall be consistent with the analytical data included in the section 1.4.

Regarding how to report the compositional information in IUCLID, the following applies: Information on each constituent and its respective concentration values is to be included in the appropriate IUCLID fields in section 1.2. Further technical details on how to report details on the constituents of a substance in IUCLID are available in section 9.4.2 of ECHA manual "How to prepare registration and PPORD dossiers" (https://echa.europa.eu/manuals).

After revision of the compositional information, you are requested to revise, in accordance with Annex VI section 2.1, the numerical identifiers such that they refer to the main constituents reported in section 1.2. The identifiers shall be sufficient to enable the registered substance to be identified.

Regarding how to report the numerical identifiers in IUCLID the following applies: the relevant appropriate CAS entry shall be included under the "CAS information" header, if available. The current CAS entry (CAS number (60304-36-1)) shall be reported under the "Related substances" header in IUCLID section 1.1. For technical reasons you are requested at this stage, not to remove or revise the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. You shall instead include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons."

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.

You acknowledged that the approach taken by you for the identification of substances manufatured by two different technologies with different reactants. ECHA understands that choice of the manufacturing process determines which of the possible constituents are present. You outlined further in your comments that the substance identification as indicated in your dossier represents rather the substance identification profile agreed upon in the SIEF than only the substance you actually manufacture. However, ECHA notes that multi-constituent sustances are defined by their composition and in particular by the main constituents. Main constituents need always be present at concentration between 10 and 80 % (w/w). The multi-constituent substance cannot be expanded by reference to other compositions with other main constituents which have same uses and properties. Moreover, you should register only the compostion your are [redacted].

1.2 Identity of the main constituent(s)

Annex VI, section 2.3. of the REACH Regulation requires that information given on composition of each substance is sufficient to enable each substance to be identified. Section 4.2.2.2 of the SID Guidance stipulates the requirements for reporting the constituents of a multi-consituent substance.

[redacted] and [redacted] are considered as constituents in their own right and shall be therefore reported separately in the substance composition. The SID Guidance specifies that all constituents present at concentration ≥ 10 %(w/w) should be reported as main constituents of the registered substance. For each constituent, a IUPAC name, numerical identifiers (e.g. EC and/or CAS information, if available) and structural formula need to be provided. Additionally, the typical, minimum and maximum concentration needs to be reported. The impurities present in a concentration ≥ 1% should be also specified. However, impurities that are relevant for the classification and/or for PBT assessment shall always be specified, irrespective of the concentration. Impurities should be specified by at least one of the following identifiers: chemical name (IUPAC and/or CAS name), CAS-number and EC-number and/or molecular formula. As a general rule, the compositional information should be completed up to 100%.

The analytical data you have included in "[redacted]" attached to section 1.4 reports three constituents, namely [redacted]. In section 1.2 of the IUCLID dossier, you have reported the [redacted] as one combined constituent under [redacted] with typical concentration of [redacted] %(w/w).

As explained above, [redacted] and [redacted] are reported jointly under one constituent in the dossier, contrary to the requirement.

In accordance with Annex VI section 2.3, you are requested to report each [redacted] and [redacted] as constituents that contribute to the composition in section 1.2 of your dossier. Each constituent present at concentration ≥ 10 %(w/w) needs to be reported as main constituents wheras each constituent present at concentration ≥ 1 %(w/w) but < 10 %(w/w) needs to be reported as an impurity.

Regarding how to report the requested information in IUCLID, the following applies; Each [redacted] and [redacted] constituent of your substance shall be reported in section 1.2. Further technical details on how to report details on the constituents of a substance in IUCLID are available in the section 9.4.2 of ECHA manual "How to prepare registration and PPORD dossiers" (https://echa.europa.eu/manuals).

2. IUPAC name (Annex VI, Section 2.1.1)

Annex IV, section 2.1.1. requires name(s) in the IUPAC nomenclature or other international chemical name(s) to be included as an identifier. Section 4.2.2.1 of the SID Guidance stipulates that a multi-constituent substance is named as a reaction mass of the main constituents of the substance.

You have selected the substance type for your substance as "multi-constituent" in section 1.1 and included the following statement in the remarks field of the reference substance "this is a multi-constituent substance". You have provided "multi-constituent substance" as a IUPAC name of your substance.

The reported IUPAC name does not provide information on the chemical identity of your substance and it is not in line with naming convention described in section 4.2.2.1 of the SID Guidance.

After revision of the compositional information as outlined in sections 1 and 2 of this decision, you are requested to revise, in accordance with Annex VI section 2.1.1, the IUPAC name such that it refers unambiguously to the composition reported in section 1.2. For example, if you have two constituents at concentration 10-80% (w/w) present in your substance, you will need to identify your substance as reaction mass of these two constituents. The IUPAC name shall be sufficient to enable the registered substance to be identified.

Regarding how to report the requested information in IUCLID the following applies; an appropriate chemical name shall be included in the IUPAC name field in section 1.1 of the IUCLID dossier. Further information on the naming of multi-constituent substance can be found in Section 4.2.2.1 of the SID Guidance.

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 October 2015.

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.

ECHA took into account your comments and amended the request(s) and the reasoning.

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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.

3. We note that you have included the following in the dossier submission remarks field in the dossier header; "In our dossier that has been submitted (Submission number [redacted]) our confidentiality claim has been requested for the detailed composition and no confidentiality has been requested for the IUPAC name." Please note that you may also include a confidentiality claim for the IUPAC name of the registered substance. You will always need to include a specific IUPAC name in your dossier; however this information will not be disseminated if you have claimed the name confidential. More information on confidentiality claims and public names can be found from ECHA manual "Dissemination and confidentiality under the REACH Regulation" available at https://echa.europa.eu/manuals.

4. In your comments to the draft decision, you refer to legal uncertainty with regard to data use rights and higher costs for registrants of the new joint submission(s). Please note that read-across may be possible between different joint submissions. If data is thus shared, additional costs can be minimized.