ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 13 March 2017

Addressee: [redacted]

Decision number: CCH-D-2114356219-45-01/F
Substance name: Phosphonium, tetrakis(hydroxymethyl)-, chloride (1:1), polymer with urea
EC number: 500-057-6
CAS number: 27104-30-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 18 November 2016
Registered tonnage band: 100-1000

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 of the registered substance (Annex VI, Section 2.1.);**

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

You may adapt the testing requested above according to the specific rules outlined in Annex VI 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 **20 June 2017**.

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.

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.

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Appendix 1: Reasons

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

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.

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement as required by Annex VI, Section 2.1 of the REACH Regulation.

The *Guidance for identification and naming of substances under REACH* and CLP (version 1.4; June 2016), thereinafter referred to as "the SID Guidance", sets the rules for naming, which are specified separately for several substance types.

According to chapter 4.2.1 of the SID Guidance a mono-constituent substance is a substance in which one main constituent is present to at least 80%. A mono-constituent substance is named after the main constituent.
According to chapter 4.2.2 of the SID Guidance a multi-constituent substance is a substance in which at least two main constituents are present with ≥10% and <80% respectively. A multi-constituent substance is named after its main constituents typically present ≥ 10% following the generic format: "Reaction mass of [names of the main constituents]".
According to chapter 4.3 of the SID Guidance the name of a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process. The generic format of the chemical name of sub-type 2 of UVCB substances is "Reaction product of [names of the starting materials]".

The registered substance has been indicated as "multi-constituent substance" in section 1.1 of the IUCLID dossier.

Additionally, the composition reported in Section 1.2 indicates that the substance contains three main constituents present typically above 10% w/w and with a substantial combined concentration of typically above 80%, which would also indicate a well-defined substance.

On the other hand the registered substance has been identified as [redacted]
(500-057-6).

The name used in section 1.1 of the IUCLID dossier to identify the registered substance is following the naming convention for UVCB substances described in section 4.3.1.2. of the SID Guidance. Also the description as "[redacted]" is indicating that the exact identity of the products is either unknown or variable. The given name is therefore indicating by content and format the substance to be of UVCB nature.

This is not in line with the composition reported in section 1.2 of the IUCLID dossier. The nature of the substance described by the name and the type are not congruent with the compositional information presented.

In line with Annex VI Section 2.1., you are required to identify the registered substance in section 1.1 of your IUCLID dossier by reference to a name that allows for an accurate and complete identification of the substance.

You shall ensure that representative identifiers are used throughout the dossier, and that these identifiers are consistent with the information on the identification of the registered substance in section 1.1, the composition in section 1.2 and the analytical data in section 1.4 of the IUCLID dossier.

Further technical details on how to report the identity of substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

In your comments to the draft decision, you agreed that the substance name and the current composition are inconsistent. You expressed your concerns that changing the registered substance type from multi-constituent substance to UVCB would also mean that the identifiers of the substance are changed. ECHA emphasises that any need to change the substance identifiers can only be determined once all the requested information is available to ECHA, and such need will be assessed in the follow-up evaluation.

ECHA also notes that you have updated your registration dossier, and ECHA has exceptionally taken the update into account for this decision making. However, you did not provide any new information regarding this request and therefore, ECHA did not amend the draft decision regarding this request.

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

Annex VI, section 2.3.7 of the REACH Regulation requires you to include descriptions of the methods used to identify and quantify the substance.

You have included several chromatographic results in the registration dossier as well as UV, IR and NMR spectra. Additionally and without corresponding results you provided the method descriptions for freeze drying the substance and for titration with iodine.

In none of these analytical attachments an attempt is made to describe how the main constituents listed in section 1.2 have been identified and quantified. Even though it is stated the "*main components and several impurities are determined using 31P NMR*", a description of the applied method, outlining how the individual constituents were identified and quantified, has not been included.

Furthermore the substance is identified as a chloride salt but none of the methods reported is suitable to identify and quantify chloride ions in the registered substance.

ECHA notes that no method of quantification present in the registration dossier has been described in such detail that the provided composition reported in section 1.2 of the dossier can be verified. The analytical methods have not been described in such detail to justify how the methods are suitable for identifying and quantifying the reported main constituents.

ECHA therefore concludes that the analytical data reported by you does not provide sufficient information regarding the quantification of all the constituents of the substance and does not enable the identity of the substance to be verified.

In line with Annex VI Section 2.3.7 you are requested to submit a suitable 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 including their counter ion if present. 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.

You shall ensure that the reported information is consistent throughout the dossier.

Regarding how to report the requested information in IUCLID, the information should be attached in IUCLID section 1.4.

In your comments to the draft decision you agreed that there is a need to improve the analytical information for the registered substance.

ECHA also notes that you have updated your registration dossier, and ECHA has exceptionally taken the update into account for this decision making. However, you did not provide any new information regarding this request and therefore, ECHA did not amend the draft decision regarding this request.

Appendix 2: Procedural history

The compliance check was initiated on 27 July 2016.

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.

You were notified that the draft decision does not take into account any updates after 3 October 2016. You updated your registration with submission number CX649231-20 on 14 November 2016. In your update the tonnage band was changed from more than 1000 tonnes per year to 100-1000 tonnes per year. You also requested ECHA to change the tonnage band of the Joint Submission from more than 1000 tonnes per year to 100-1000 tonnes per year. ECHA made the requested joint submission tonnage band change on 7 November 2016. Exceptionally therefore, and given the specific circumstances of this case, ECHA has taken into account the update of 14 November 2016 in this decision.

ECHA took into account your comments, and the tonnage band downgrade, and amended the requests and the deadline.

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. In relation to the information required by the present decision, the sample of the substance used for the new test(s) 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 compositions 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. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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.