ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306151-69-01/F Helsinki, 7 August 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts, CAS No 84605-29-8 (EC No 283-392-8), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts, CAS No 84605-29-8 (EC No 283-392-8), submitted by [redacted] (Registrant).

The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after the deadline for updating (25 March 2015) communicated to the Registrant by ECHA on 16 February 2015.

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

The compliance check was initiated on 9 January 2014.

On 9 January 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 16 February 2015 the Registrant did not provide any comments on the draft decision to ECHA.

On 11 June 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI Section 2.1.);
2. Composition of the substance (Annex VI, 2.3.);
3. The High-pressure liquid chromatogram or Gas chromatogram (Annex VI, 2.3.6.);
4. The description of the analytical methods (Annex VI, 2.3.7.).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **15 February 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Information in the technical dossier related to the identity of the substance

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.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1. of the REACH Regulation. 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.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) 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: 1.3, February 2014) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient information on the manufacturing process, as explained below.

The registered substance corresponds, according to the chemical name assigned by the Registrant in section 1.1 of the IUCLID dossier, to Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts. For this substance, the Registrant provided, in IUCLID section 3.1, a description of the manufacturing process indicating that the substance is produced in two main steps. However, the description does not contain information on the ratio of the starting materials. Also the specific process parameters relevant for controlling the manufacturing process are not given (e.g. temperature, end of

reaction criteria, etc). This information is necessary to reach a level of detail sufficient to enable the identification of the registered substance.

Therefore, the Registrant is requested to provide information on the ratio of the starting materials used for the manufacturing of the registered substance in the Description field in IUCLID section 1.1.

The Registrant shall ensure that the information is consistent throughout the dossier. Where the Registrant covers different grades of the substance in a registration, the Registrant shall report separately the source, manufacturing process of each grade.

2. Composition of the substance (Annex VI, 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.

According to section 4.3 of the Guidance, for UVCB substances such as the registered substance, 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. Regarding the ZDDP forms it is expected as a minimum to report separately generic entries corresponding to the neutral and basic forms, in line with the provided analytical data.

For each constituent and group of constituents, the minimum, maximum and typical concentration, shall be reported.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity. More specifically, ECHA notes that one generic reference substance covering all constituents of the UVCB substance has been reported in the IUCLID section 1.2. ECHA also notes that in IUCLID section 1.1 the Registrant reported in the remarks field of the Structural formula that "*There are three major structural types present in all zinc dialkyldithiophosphate (ZDDP) products: Neutral...(1) Monomer: $Zn(DDP)_2$... (2) Dimer: $Zn_2(DDP)_4$...*" and "*(3) Basic: $Zn_4O(DDP)_6$...*". However, individual entries with the compositional information of the neutral (monomer and dimer) and basic forms of the ZDDP are missing from IUCLID section 1.2.
ECHA also notes that all the analytical analyses show the presence of "*process oil*", however the nature and origin of the "*process oil*" is not described in the registration dossier.

Therefore, the Registrant is requested to submit the identity and concentration values of the constituents and groups of constituents required to be reported in the composition.
The Registrant shall ensure that the information is consistent throughout the dossier.

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the compositional information of each grade.

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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

Note for the consideration of the registrant

The Registrant should note that in line with Article 3(1) of the REACH Regulation, in case the "*process oil*" is a solvent, the quantity of solvent which can be removed without affecting the stability or changing the composition of the registered substance should be excluded from the substance for all reporting and testing purposes. In that case, the Registrant should list the "*process oil*" as constituent of the substance and shall report the quantity of "*process oil*" which cannot be removed without affecting the substance stability in the compositional information in IUCLID section 1.2. The identification of the nature and origin of the "*process oil*" would be therefore an essential element for the identification of the registered substance. Therefore, in case the "*process oil*" is actually a solvent the Registrant would need to include information on the identity of the "*process oil*" in terms of qualitative and quantitative information on the different constituents and/or group of constituents. In such a case, the Registrant would also need to provide the description of the analytical methods used to determine the overall quantity of the "*process oil*" which cannot be removed without affecting the stability of the substance or changing its composition. The information shall be sufficient for ECHA to conclude that all the relevant physical and chemical methods have been evaluated to extract the constituents from the "*process oil*".

3. The High-pressure liquid chromatogram or Gas chromatogram (Annex VI, 2.3.6.)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the provided High-pressure liquid chromatographic (HPLC) has not been reported in sufficient detail. More specifically the chromatogram provided in IUCLID section 1.4 contains a peak at 2.66 minutes that is attributed in the HPLC peak list to "*process oil*". However, the area of the peak is not reported and therefore is not possible to verify the amount of "*process oil*" present in the substance and consequently is not possible to verify the composition of the substance.

Therefore, the Registrant is requested to submit a chromatographic report with the respective peak list providing the retention time and peak area for all the peaks present in the chromatogram.

The Registrant shall ensure that the information is consistent throughout the dossier. As for the reporting of the chromatographic data in the dossier, the information shall be attached in IUCLID section 1.4.

4. The description of the analytical methods (Annex VI, 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement. ECHA observes that the Registrant did not provide sufficient 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, as required according to Annex VI section 2.3.7.

More specifically, ECHA notes that the dossier is missing the description of the methods necessary to establish the composition of the registered substance to the level of detail specified in section III.A.2 of this decision and required for the identification of the registered substance. In addition, the description of the methods used for the identification and quantification of the zinc present in the substance is missing from the dossier.

ECHA also notes that, as mentioned before in section III.A.2, all the analytical analysis was done in the presence of "*process oil*". The Registrant should note that all analysis has to be performed with the substance as manufactured, with only the amount of solvent which cannot be removed without affecting the substance stability.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a 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 and of the zinc present in the 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. The Registrant shall ensure that the information is consistent throughout the dossier.
As for the reporting of the above data in the registration dossier, the information should be attached in IUCLID section 1.4.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[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.