ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306174-61-01/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 submitted 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

A. 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, 2.1.);
2. Composition of the substance (Annex VI, 2.3.);
3. Spectral data (Annex VI, 2.3.5.).

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

A. 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" hereinafter. 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. "[redacted]".

The ratio of all the starting materials is missing in the registration dossier. In addition, the specific identity of the oil (e.g. chemical name, EC/List and/or CAS entries) used in the second step is not described with enough detail. Also the specific process parameters

relevant for controlling the manufacturing process are not given (e.g. temperature, end of reaction criteria, etc).

Therefore, the Registrant is requested to provide information on the ratio and identity of all starting materials and for all steps of the manufacturing process the relevant corresponding operating parameters. The Registrant shall ensure that the information is consistent throughout the dossier. If the Registrant covers different grades of the substance in a registration, the Registrant shall report separately the source and the manufacturing process of each grade.

The information shall be included in the Description field in IUCLID section 1.1.

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.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity.

a) Constituents of the substance

ECHA notes that one generic reference substance covering [redacted]% of the constituents of the UVCB substance and two other constituents (2-ethylhexan-1-ol and propan-2-ol) listed as impurities, have been reported in the IUCLID section 1.2. ECHA also notes that in IUCLID section 1.4 the Registrant submitted a report ("[redacted]") where it is stated that "There are three major structural types present in all zinc dialkyldithiophosphate (ZDDP) products: Neutral...(1) Monomer: Zn(DDP)2 ... (2) Dimer: Zn2(DDP)4..." and "(3) Basic: Zn4O(DDP)6..." and that in the report "[redacted]" submitted as well in IUCLID section 1.4 the basic and neutral forms of the ZDDP are determined from % mole values of the different ZDDP forms obtained by 1HNMR results. However, this more detailed composition with individual entries for the neutral (monomer and dimer) and basic forms of the ZDDP are missing from IUCLID section 1.2.

Therefore, the Registrant is requested to provide the following information regarding the identification of constituents of the registered substance:

- All constituents present in the substance with a concentration of ≥ [redacted] % 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. The registrant may refer to section 4.3 of the Guidance for further details.

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.

b) Additives

ECHA notes the presence of two additives (Distillates (petroleum), hydrotreated heavy paraffinic (EC 265-157-1) and Distillates (petroleum), solvent-dewaxed heavy paraffinic (EC 265-169-7)) in the composition which are reported to have stabilising effect.

In accordance with section 2.2 of the Guidance, an additive is a "substance that has been intentionally added to stabilise the substance". Other intentionally added substances that have other functions than to stabilize the registered substance are not part of the registered substance and shall not be reported as an "additive" in the composition.

The registration lacks information about the application of these two petroleum products in the description of the manufacturing process. On this basis it cannot be confirmed that the two petroleum products have a stabilization function. Additionally, it is reported that the two ZDDP forms cover [redacted]% of the substance composition, which gives an indication that the substance is stable without the presence of any additive. Moreover, there is indication from a scientific literature reference provided by the Registrant that the chemical integrity of this type of substances does not depend on the use of stabilisers.

Therefore the Registrant shall clarify the function (e.g. additives or solvent) of the two petroleum substances reported as stabilizers and shall revise the information on additives accordingly, i.e. in line with the applicable option below:

- If the reported additives do not have stabilising effect, they are not considered as part of the substance and shall not be listed under additives.

- In case the Registrant considers the distillates to be correctly reported as additives, a justification shall be provided demonstrating the stabilising effect of the additives. Such a justification shall contain sufficient detail on the function of the additive to allow the Agency to verify that the primary function of the additive is indeed to preserve the stability of the substance. Additionally, the Registrant would need to include information on the identity of the distillates in terms of qualitative and quantitative information on the different hydrocarbon classes (including linear alkanes, branched alkanes, cycloalkanes, mono-/di-/tri-... aromatic hydrocarbons and other groups of constituents (if present))and on the carbon number distribution within each of these classes. Additionally, all constituents ≥ 10 % (w/w) need to be identified and all constituents relevant for classification and labelling and/or PBT assessment (e.g. benzene, toluene, 1,3-butadiene) shall be identified, quantified and reported individually irrespective of their concentration.

Note for consideration by the Registrant:

In the absence of a primary stabilisation function, the distillates could be regarded as solvents. In case the distillates are actually solvents, the Registrant should note that in line with Article 3(1) of the REACH Regulation, the quantity of distillates which can be removed without affecting the stability or changing the composition of the registered substance should be excluded. In that case, the Registrant should list the distillates as constituents of the substance and shall report the quantity of distillates which cannot be removed without affecting the substance stability in the compositional information in IUCLID section 1.2. The identification of the specific solvents used during the manufacturing process would be therefore an essential element for the identification of the registered substance. Therefore, in case the distillates are actually solvents the Registrant would need to include information on the identity of the distillates with the same level of detail as requested above in case the distillates are considered additives.

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 distillates 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 distillates. The Registrant shall ensure that the information is consistent throughout the dossier.

3) The spectral data (Annex VI, 2.3.5. of the REACH Regulation)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation.

ECHA notes that the proton nuclear magnetic resonance (1H –NMR) spectrum provided in IUCLID section 1.4 is missing the integral curves and/or numerical integral values for the relevant signals. These integrals are required to verify the expected ratios of hydrogen atoms in the registered substance. Without this information it is not possible to verify the identity of the registered substance.

Therefore, the Registrant is requested to submit a 1H-NMR spectrum with the respective integral curves and/or numerical integral values for the relevant signals derived from the registered substance subject to the present decision.

The Registrant shall ensure that the information is consistent throughout the dossier. As for the reporting of the spectral data in the registration dossier, the spectra shall 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.