EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003066-79-03/F Helsinki, 13 March 2013

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

For Reaction products of bis(4-methylpentan-2-yl)dithiophosphoric acid with phosphorus oxide, propylene oxide and amines, C12-14-alkyl (branched) (List No 931-384-6), 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 dossier for Reaction products of bis(4-methylpentan-2-yl)dithiophosphoric acid with phosphorus oxide, propylene oxide and amines, C12-14-alkyl (branched) (List No 931-384-6) submitted by [redacted] (Registrant).

This decision is based on the registration dossier 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 18 January 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation. The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 18 October 2012.

On 23 November 2012 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 02 January 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 18 January 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below.
b. Composition of the substance (Annex VI, 2.3.), as specified under section III.(b) below.
c. Description of the analytical methods (Annex VI, 2.3.7.), as specified under section III.(c) below.

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III. below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **13 June 2013.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is required to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

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

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 should consist of two parts: the chemical name and 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: 1.2, March 2012) - referred to as "the Guidance" hereinafter. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported.

ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance (as explained under points (i) and (ii) hereinafter).

(i) The Registrant specified a chemical name for the registered UVCB substance referring to the reaction products of the starting materials used for its manufacturing. However, some of the reacting materials have not been identified specifically enough. ECHA observes that the names used to refer to the starting material are not exact enough to be considered appropriate. In particular a) the term "bis(4-methylpentan-2-yl)dithiophosphoric acid" may refer to O or S bound substituents and b) the term "phosphorus oxide" is ambiguous as phosphorous can form multiple oxides of different composition.

(ii) ECHA observes that the description of the manufacturing process necessary for the identification of the registered substance has not been provided. The naming convention followed by the Registrant for the identification of the alkylamine starting material pertains to UVCB substances with variation in the carbon chain length. However, ECHA points out that UVCB substances such as this starting material cannot be sufficiently identified by a chemical name only. Compositional information of that starting material (in terms of identity and upper and lower concentration levels of the alkylamines individually and/or grouped by carbon number) is a necessary element for its identification and therefore for the identification of the registered substance itself.
Other elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. In particular, the ratio of reactants used and specifications of any other manufacturing process parameters determining the degree of completion of the reaction have not been indicated.
ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered UVCB substance.

In line with the observations under point (i) above, the Registrant is required to specify an appropriate chemical name for the registered UVCB substance. The Registrant shall ensure that the chemical name is representative of the specific substance which is the subject of this registration. The Registrant shall note that, although the List number 931-384-6 currently assigned to this registration refers to the inappropriate chemical name currently specified in the dossier, the Registrant shall not modify or delete at this stage the List number for technical reasons, the registration being linked to that List number in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the List number currently assigned does not specifically correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

In line with the observations under point (ii) above, the Registrant shall provide the missing information on the manufacturing process description. This information shall include:

- Compositional information of the starting material in terms of identity and upper and lower concentration levels of the individual alkylamines and/or of the alkylamines grouped according to their carbon numbers, and
- Ratio of reactants, and
- Specifications of the relevant process parameters, including appropriate solvent, temperature, catalyst and end-of-reaction parameters.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the source, manufacturing and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration.

As for the reporting of the information in IUCLID, the chemical name and the description should be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively. Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1. The Registrant should specify, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The List No 931-384-6 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update". The Registrant should also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

The Registrant shall ensure that the chemical name assigned to the registered substance is consistent with the compositional information specified in the dossier. The Registrant shall also ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

(b) Composition of the substance (Annex VI, 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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH, the Registrant should note that, 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 reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. For the registered substance, the reporting of unknown

constituents according to the ^{31}P NMR analysis page 1 seems appropriate. For each group of unknown constituents, a structural representation according to the identity of the constituents of the starting material and the possible reactions involved in the polymerisation is appropriate.

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

In line with the above, the Registrant is required to provide any information which is suitable and necessary for ECHA to use the compositional information as one identifier for the registered substance. The Registrant must provide any information which is suitable and necessary to meet these objectives.

Regarding how to report the composition of UVCB substances in IUCLID, further technical information is provided 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) - referred to as "the Data Submission Manual 18" hereinafter - available on the ECHA website.

Where the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade.
This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of the Data Submission Manual 18, available on the ECHA website. ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration. The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the required analytical data included in IUCLID section 1.4. The Registrant shall ensure in particular to remove any analytical information which has not been generated on the substance which is the subject of this registration and replace it with data carried out on the registered substance, as appropriate.

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

ECHA observes that the Registrant did not provide any description of the analytical method used for the identification and quantification of the alkylamine component present in the registered substance, which is required according to Annex VI section 2.3.7. The Registrant also does not provide a detailed description of the calculation used to derive the quantitative results reported on page 1 of the analytical report [redacted]. Specifically it is not clear based on the current information i) how the species were differentiated and ii) how the weight percentages were derived from the initially obtained mole percent.

The Registrant is accordingly required to provide a description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered 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.

As for the reporting of the 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
Director of Regulatory Affairs