ECHA
EUROPEAN CHEMICALS AGENCY

Final decision: CCH-D-0000001589-63-10/F Helsinki, 27 March 2012

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

For Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide, CAS No 162881-26-7 (EC No 423-340-5), 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 Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide, CAS No 162881-26-7 (EC No 423-340-5), submitted by [redacted] (the Registrant), latest submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

The compliance check was initiated on 19 May 2011.

On 11 July 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 10 August 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and amended the draft decision accordingly.

On 4 November 2011 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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 8 December 2011 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to modify the draft decision.

On 19 December 2011, the draft decision was referred to the Member State Committee.

On 9 January 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 6-10 February 2012, the Member State Committee further modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 8 February 2012.

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

II. Information required

Pursuant to Articles 41(1)(c), 14 and Annex I of the REACH Regulation, the Registrant shall provide and submit in an updated chemical safety report:

a. PNEC for the aquatic and sediment compartments. Alternatively, the Registrant may clearly state and fully justify, as specified in section III, 2a) below, why it is not possible to derive PNECs for the aquatic and/or sediment compartments;
b. Predicted Environmental Concentrations (PEC) for the terrestrial and sediment compartments; and
c. Exposure scenarios and exposure estimations for the waste life stage of the registered substance. Alternatively, the Registrant may clearly document and justify in the CSR why there is no need to carry out a more detailed exposure assessment.

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 **27 September 2012**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

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 100 to 1000 tonnes per year in accordance with Article 6, does not comply with the requirements of Articles 10, 12, 13 and 14, as well as with Annexes I, VI and IX thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Information related to the chemical safety report

Article 14 and Annex I set out the general provisions for assessing substances and preparing chemical safety reports (CSR).

(a) Predicted No Effect Concentration (PNEC) for the aquatic and sediment compartments

Annex I, section 3.3 of the REACH Regulation, requires the Registrant to establish predicted no effect concentrations (PNEC(s)) for the registered substance, *"covering each environmental sphere"*. The footnote to Annex I, section 3.3.1 provides further information

on the application of assessment factors to cover the uncertainty associated with the available data, which is further explained in the ECHA guidance Chapter R.10. According to Annex I, section 3.3.2, where the derivation of PNEC is not possible, this must be clearly stated and fully justified.

ECHA notes that, under paragraph 7.1.2, Calculation of Predicted No Effects Concentration, the CSR submitted by the Registrant contains PNECs for the aquatic compartment. For aquatic PNEC derivation, the Registrant has applied no assessment factor (AF) but reported instead the presumed water solubility of the substance as a substitute for the PNEC. ECHA concludes that this approach is not in line with the provisions of the footnote to Annex I, section 3.3.1 and of ECHA Guidance chapter R.10, section R.10.3.1.2. Consequently, the derived aquatic PNECs are invalid. The Registrant shall therefore provide revised aquatic PNEC derivations in line with the provisions of Annex I as indicated above.

ECHA further notes that the PNEC for sediment is missing from the CSR, which has not been fully justified, as required by Annex I, section 3.3.2. The justification provided by the Registrant, that the PNEC for freshwater and marine sediment *"cannot be derived exclusively via EPM"*, is not sufficient. In this respect, ECHA recognises that, as further explained by the Registrant, the use of the Equilibrium Partitioning Method (EPM) alone is not sufficient, due to its uncertainty, to fulfil the requirements of Annex IX in relation to risk assessment. ECHA also recognises that the use of EPM is not possible for highly insoluble substances, for which no effects are observed in aquatic studies. ECHA, however, points out that despite these limitations, the use of EPM provides an estimate of the risk to which the sediment compartment is exposed, which could prompt the Registrant to consider the need for further studies. Furthermore, the Registrant is reminded that according to ECHA Guidance chapter R.7b, section R.7.8.12.2, when the application of EPM is not possible, such as in the case of substances with high insolubility and no effects on aquatic organisms, the Registrant shall consider performing one sediment test instead.

The Registrant is therefore requested to establish the appropriate PNECs for the aquatic and sediment compartments and to update the CSR accordingly. Alternatively, the Registrant may clearly state and fully justify, as explained above, why it is not possible to derive PNECs for the aquatic and/or sediment compartments and update the CSR accordingly.

In case any PNECs are derived the Registrant is reminded that these PNECs should be applied to the characterisation of risk, as enunciated by Annex I, section 6. The Registrant is also reminded that a quantitative exposure assessment should also be generated, in case the outcome of the risk characterisation indicates a risk for any environmental compartment.

(b) Predicted Environmental Concentrations (PEC) for the terrestrial and sediment compartments

Annex I, section 5.2 of the REACH Regulation, requires the Registrant to provide exposure estimations, taking into consideration *"the duration and frequency of emissions of the substance to the different environmental compartments and the dilution in the receiving environmental compartment"* for the registered substance, *"covering each environmental sphere"*.

ECHA notes that, under paragraph 9.7.2, Exposure estimations, the CSR submitted by the Registrant does not contain PEC values for the terrestrial and sediment compartments. The estimation of PECs is a core part of exposure assessment, and it allows comparisons of

PNECs with concentrations predicted for individual environmental compartments to address risk. The justification provided by the Registrant indicates that the model applied for the calculations of PEC for sewage treatment plants is not applicable to the calculation of PECs for terrestrial and sediment compartments. Nevertheless, this statement does not release the Registrant from its obligation to provide an estimate of predicted environmental concentrations for these compartments. The Registrant shall therefore provide PEC estimations for the terrestrial and sediment compartments.

The Registrant is reminded that these PECs should be applied to the characterisation of risk, as required by Annex I, section 6.

(c) Information on waste life stage

Annex I, section 5 of the REACH Regulation, requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. According to ECHA Guidance chapter R.18, section R.18.2.3.1, "*an upfront conclusion that there is no need to carry out a more detailed exposure assessment for the waste stage should be well documented and justified in the CSR*".

ECHA observes that in the provided CSR the Registrant reports no exposure scenario or exposure estimation for the waste life stage. Although the Registrant indicates that during manufacturing any process water will be handled by and external certified waste treatment company, it is not clear whether there may be any waste originating from other exposure scenarios linked to both industrial and wide dispersive use applications. Therefore, exposure to the registered substance at the waste stage, especially at the end-of-life stage of matrices, coatings and products containing the substance, is not excluded. These potential exposures are to be reported in exposure scenarios 2 to 7 in the CSR.

The Registrant is accordingly requested to generate exposure scenarios and exposure estimations for the waste life stage of the substance and to update the CSR for this endpoint. Alternatively, the Registrant should clearly document and justify in the CSR why there is no need to carry out a more detailed exposure assessment.

2) Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 12 months from the date of the adoption of the decision. This period of time took into account the fact that the draft decision also requested a bioaccumulation study. As this study is no longer requested in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds Registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> "Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or

other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

V. 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]

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