EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002166-78-03/F Helsinki, 12 March 2012

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

For Phenol, isobutylated, phosphate (3:1) CAS No. 68937-40-6 (EC No. 273-065-8), 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 the ECHA has performed a compliance check of the registration dossier for Phenol, isobutylated, phosphate (3:1), CAS No. 68937-40-6 (EC No. 273-065-8) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 11 November 2011.

On 2 December 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.

The Registrant did not provided to ECHA comments on the draft decision.

On 20 January 2012 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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.

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. The name or other identifier (Annex VI, Section 2.1.). Any information which is suitable and necessary to allow ECHA to identify the name of the registered substance as specified under point III.1)(a) below;

b. Composition of the substance (Annex VI, Section 2.3.). Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under point III.1)(b) below;

c. The description of the analytical methods for the identification of the substance (Annex VI, Section 2.3.7.) as specified under point III.1)(c) below.

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 **14 May 2012**.

III. Statement of reasons

Based on the examination of the technical dossier (targeted on substance identity endpoints), 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 Articles 10 and Annexes VI 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.

Missing information related to substance identity

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 identifiers (Annex VI, Section 2.1.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

The Registrant identified the registered substance as a multi-constituent substance. However, ECHA notes that the Registrant did not specify any appropriate name for such well-defined substance, as required under Annex VI, Section 2.1.

More specifically, the Registrant assigned an EC entry with EC name "Phenol, isobutylenated, phosphate (3:1)". This entry corresponds to a triphenyl phosphate where at least the relative position of the isobutyl substituent on the phenol moiety is undefined. However, ECHA observes that the NMR spectral data attached in the dossier indicates that the registered substance includes the isobutyl substituent as a tert-butyl group in para-position of the phenol moiety. It follows that the assigned EC entry does not specifically correspond to the substance. For the same reasons, the CAS entry with CAS number 68937-40-6 is not an appropriate identifier of the registered substance.

Following section 4.2 of the "Guidance for identification and naming of substances under REACH"[1], the Registrant should note that multi-constituent substances are named using the format "Reaction mass of [main constituents]", wherein the main constituents are those typically ≥ 10%. The main constituents should be named according to the IUPAC nomenclature rules.

In line with the above, the Registrant is requested to specify the chemical name corresponding to the registered multi-constituent substance in order to allow ECHA to establish the name and other identifier of the registered substance.

Regarding how to report the chemical name, the information shall be included in the IUPAC name field of IUCLID section 1.1

The Registrant shall ensure that the chemical name is consistent with the information on the composition reported in IUCLID section 1.2.

(b) Composition of the registered substance (Annex VI, Section 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 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.

More specifically, ECHA notes that the Registrant did not correctly identify two (2) of the four (4) constituents listed in the composition. The para- position of the tert-butyl substituent of the relevant phenol moieties has been correctly represented neither in the EC, CAS or IUPAC identifiers nor in the molecular and structural information assigned to the 2 first listed constituents.

In addition, ECHA notes that the description of the manufacturing process reported in the chemical safety report (CSR) attached in the dossier indicates that "*The [redacted] used in production distinguishes the different products*". It implies that the relative ratio of the 4 constituents reported in the composition can be adjusted for the manufacturing of different grades. ECHA observes that two (2) of the four (4) constituents, tris(4-tert-butylphenyl) phosphate and triphenyl phosphate, overlap the [redacted]. Depending on the manufactured grade, these constituents will or will not be the main constituents. ECHA therefore concludes that the reported composition covers more than one multi-constituent substance. In line with chapter 5 of the "Guidance for identification and naming of substances under REACH", the Registrant should note that multi-constituent substances having different main constituents are regarded as different substances.

Accordingly, the Registrant shall revise the EC, CAS and IUPAC information as well as the molecular and structural information used to identify the 2 first constituents. The Registrant is also requested to revise the concentration ranges of the constituents reported in section 1.2 so that only the grade(s) referring to the same substance are covered by the composition. The Registrant shall note that a separate registration shall be submitted for

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach

any other grade having different main constituents than the registered substance. The Registrant shall also ensure that the degree of purity provided in section 1.2 is representative for the registered multi-constituent substance. Therefore the concentrations of all main constituents present in the substance shall be considered.

Regarding how to report the composition of the multi-constituent substances in IUCLID, further technical information is provided in paragraphs 2.1 and 2.2.1.2 of the Data Submission Manual 18 available of the ECHA website.[2]

The Registrant shall ensure that that the composition is consistent with the identifiers to be reported in IUCLID section 1.1 and is supported by the required analytical data in IUCLID section 1.4. In particular, the Registrant shall replace any analytical information which has been generated on a grade which is not covered by the registration with data generated on the registered substance.

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

The Registrant provided the results of a method for the quantification of the reported constituents based on a chromatographic analysis and the corresponding chromatograms. However the report from the chromatographic analysis, including peak table with the peak areas and details of the calculations made for the quantification of the constituents are missing. The description of the analytical method used for the quantification of the registered substance is therefore not sufficiently detailed for the method to be reproduced, as required in Annex VI, Section 2.3.7.

Accordingly, the Registrant is requested to submit the missing information on the description of the analytical method(s) used for the quantification of the registered substance.

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://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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Director of Regulatory Affairs

[2] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration