ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003568-65-07/F Helsinki, 17 March 2014

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

For tris(methylphenyl) phosphate, CAS No 1330-78-5 (EC No 215-548-8), 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 tris(methylphenyl) phosphate, CAS No 1330-78-5 (EC No 215-548-8) 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 31 October 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.

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 28 February 2013.

On 26 April 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 27 May 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 31 October 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 submitted proposals for amendment to the draft decision.

On 5 December 2013 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 on the proposal for amendments within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 16 December 2013 ECHA referred the draft decision to the Member State Committee.

By 7 January 2014 the Registrant did not provide any comments on the proposals for amendment. However, the Registrant provided comments on the draft decision. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 January 2014 in a written procedure launched on 10 January 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

Pursuant to Articles 41(1)(a), 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:

a) Name or other identifier of the substance (Annex VI, 2.1.);
b) Information on the percentage of (significant) main impurities (Annex VI, 2.3.3.), and in particular information relating to the presence of ortho-isomers of tris(methylphenyl) phosphate in the substance;
c) Composition of the substance (Annex VI, 2.3.).

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 **17 June 2014.**

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.

1. 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.

a) Name or other identifier of the substance (Annex VI, 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 information provided on the identity of the registered substance is inconsistent.

More specifically, in section 1.1 of the IUCLID dossier the indicated IUPAC name, structural formula, InChI and SMILES notations refer to a specific isomeric form of tricresyl phosphate (tris(4-methylphenyl) phosphate), whereas the provided EC (215-548-8) and CAS (1330-78-5) identifiers are nonspecific, generic entries for a tricresyl phosphate. Identifying the substance with such generic EC and CAS entries would imply that the substance is composed of all possible isomers of tricresyl phosphate as main constituents. ECHA emphasizes that in accordance with Annex VI, section 2 of the REACH Regulation these generic EC and CAS entries cannot cover any specific isomer or a combination of limited number of isomers of tricresyl phosphate. Furthermore, the compositional information provided in section 1.2 and the analytical data attached in section 1.4 of the IUCLID dossier do neither confirm the predominance of a specific isomer nor the presence of all possible isomers of the tricresyl phosphate (see point III c for more details).

In his comments on the draft decision, the Registrant specified the way he proposes to revise the registration dossier in order to address the incompliances identified by ECHA. The Registrant claimed that he intends to replace the name currently specified in the IUCLID dossier with the name "tris(methylphenyl)phosphate". In addition the Registrant intends to modify the structural information included in section 1.1 of the IUCLID dossier in order to reflect such naming. ECHA observes that such a name describes a substance including all possible isomers of tris(methylphenyl)phosphate (o,o,o-isomer, o,o,m-isomer, o,o,p-isomer, m,m,m-isomer, m,m,o-isomer, m,m,p-isomer, p,p,p-isomer, p,p,o-isomer, p,p,m-isomer, o,m,p-isomer) as main constituents and does not correspond to a substance that includes a limited number of isomers of tris(methylphenyl)phosphate. ECHA notes also that the Registrant stated in his comments that the registered substance includes o-methylphenyl isomers only in trace amounts. This means that o-methylphenyl isomers are not present in the substance as main constituents. Therefore the registered substance does not include all possible isomers of tris(methylphenyl)phosphate as main constituents.

ECHA observes that the Registrant explained that the approach proposed for naming the registered substance would be in accordance with Data Submission Manual Part 18 (Q&A7). The Registrant should note that Q&A7 of the manual states: "Provided your well-defined substance consists of all possible stereoisomeric forms as the main constituents of that substance, you can identify your substance in section 1.1 using only the IUPAC name of the substance without specifying the stereochemistry." (emphasis added). As underlined in the above-sentence the approach proposed can be followed only if all possible forms are present as main constituents.

Furthermore ECHA notes that the Registrant included two compositional information sets in section 1.2 of the IUCLID dossier. One compositional block includes the following constituents each present in the substance with concentration levels [redacted]%:

[redacted]

The second composition block includes the following constituents each present in the substance with concentration levels [redacted]%:

[redacted]

From the information given in the IUCLID dossier and the information provided by the Registrant in his comments it can be concluded that the registered substance does not include all possible isomers as main constituents.

ECHA calls the Registrant's attention to the fact that the name included in the "IUPAC name" field in section 1.1 of the IUCLID dossier shall reflect the specific identity of the registered substance. In accordance with section 4.2.2.1 ("Multi-constituent substances-Naming convention") of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012, referred to as "the Guidance" thereinafter), multi-constituent substances are well-defined substances in which more than one constituent is present at a concentration ≥10% (w/w) and <80% (w/w) (referred to thereinafter as "main constituent"). A multi-constituent substance is named as the reaction mass of the main constituents.

ECHA points out that, in accordance with the criteria for substance sameness specified in paragraph 5 of the Guidance, multi-constituent substances with different main constituents shall be regarded as different substances under REACH. ECHA therefore concludes that the provided EC and CAS entries, chemical name and the composition specified in the dossier may refer to different substances. In addition, as explained above, the two composition blocks included in section 1.2 of the IUCLID dossier potentially indicate two different substances: [redacted] Different substance would need to be registered individually.

Accordingly, the Registrant is requested to clarify the identity of the substance by providing consistent name and other identifiers of the substance. The appropriate chemical (IUPAC) name and other identifiers, including the EC and CAS entries, shall be included in the corresponding fields of IUCLID section 1.1.

Concerning the modification of the chemical (IUPAC) name, in accordance with section 4.2.2.1 ("Multi-constituent substances-Naming convention") of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012), the multi-constituent substance shall be named as the reaction mass of its main constituents, including its specific isomers.

Concerning the modification of the CAS identifier, if none of the existing CAS entries can precisely describe the registered substance, the CAS field shall be left empty and the CAS number 1330-78-5 shall be moved to the "Related CAS information" field, if appropriate.

Concerning the modification of the EC identifier, the Registrant is requested not to remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT. Such modification can therefore only be made by ECHA, which has established a process allowing registrants to adapt the EC identifier initially indicated in the IUCLID dossier when it is not correctly describing the identity of the registered substance. In order to allow such modification of the dossier, the Registrant shall submit a request through the "ECHA Helpdesk contact form", accessible on ECHA's website, at the following link: http://echa.europa.eu/contact/helpdesk-contact-form.

The identifiers adaptation process will apply as follows. This request shall include the chemical name corresponding to the substance that is actually manufactured or imported. If the modification concerns a joint submission involving multiple registrants of the same substance, the adaptation of identifiers requires the agreement in writing on the modification from every other registrant concerned. Upon receipt of a complete request, ECHA will perform the technical modifications in REACH-IT and will inform the Registrant when the change was performed. The Registrant will then be asked to update the registration dossier with the new identifier.

In order to comply with the present decision pending the completion of the identifier modification process, the Registrant is requested to include the following text in the "Remarks field" of the reference substance:

> "*The EC entry currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons, but a request has been submitted to ECHA in that respect*".

Finally, the Registrant shall ensure that the chemical (IUPAC) name is consistent with the information on the composition reported in IUCLID section 1.2. According to section 4.2.2 of the Guidance for identification and naming of substances for REACH and CLP, only main constituents typically present at ≥10% contribute to the name.

b) Percentage of (significant) main impurities (Annex VI 2.3.3.)

Based on the proposal for amendment submitted by the Dutch Competent Authority underlining the need for clarification in relation to the presence of ortho-isomers of tris(methylphenyl) phosphate in the registered substance, ECHA notes that such need for clarification is driven by the potential neurotoxic properties of these specific isomers and by the general applications/uses of the registered substance described in the technical IUCLID dossier (e.g. the presence of ortho-isomers of tris(methylphenyl) phosphate in [redacted] cannot be excluded and raises concerns in relation to the potential human exposure to neurotoxic isomers).

The concern raised is further related to the fact that ortho-isomers of tris(methylphenyl) phosphate (CAS 78-30-8) are subject to harmonised classification. According to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation), harmonised classification in particular for STOT SE1 classification is triggered at a lower concentration level than 1% (it should be noted that STOT SE2 classification already applies at a concentration limit of 0.2%). No

specific information is provided in the registration dossier regarding the concentration levels of these isomers. Such information is needed to determine the possible impact of the isomeric composition of the substance on the toxicological properties of the substance.

In his comments to the draft decision, the Registrant stated that "the tris(methylphenyl) phosphate contains *m*-, *p*- and *o*-methylpenyl groups, the latter being present in traces". ECHA notes that such information indicates that the presence of ortho-isomers cannot be excluded from the composition of the registered substance.

Furthermore, ECHA notes that the analytical data in the current registration dossier does not provide any information on how the Registrant determined the concentration levels of the ortho-isomers in the composition of the registered substance in order to conclude on the classification and labelling of the registered substance.

ECHA recognises that in line with the Guidance, "*impurities present in a concentration ≥ 1% (or above any lower concentration limit, if relevant for the classification of the substances) should be specified by at least one of the chemical identifiers*". However ECHA is not in the position to verify that the concentration level of the ortho-isomers is such that these impurities are required to be reported in the IUCLID dossier.

Therefore ECHA concludes that the current compositional information on the contribution of the ortho-isomers of tris(methylphenyl) phosphate, which are expected to be present and are of significance in the determination of the classification and labelling and/or risk assessment of the registered substance, requires further clarification for a unambiguous identification of the substance.

The Registrant is accordingly requested to revise the composition of the registered substance. For this purpose, the Registrant shall provide information on the cumulative maximum, minimum and typical concentration values of the ortho-isomers of tris(methylphenyl) phosphate. The Registrant is requested 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 multi-constituent substances in IUCLID, further technical information is provided in paragraph 2.2.1 of the Data Submission Manual 18 available on the ECHA website.

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.

c) 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 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 two compositions are reported in IUCLID section 1.2: [redacted]). This indicates that these two compositions refer to two different substances which may have different hazardous properties that need to be understood and assessed separately.

In his comments on the draft decision, the Registrant claims that the substance contains "*m-, p- and o-methylpenyl groups, the latter being present in traces*". The Registrant accepts the requirement to complete the composition in order to include all the constituents and impurities. However, the Registrant is committed to "*revise the compositional information in the dossier to one composition only covering both grades in accordance with current analytical data*". ECHA underlines that according to the Data Submission Manual Part 18, (Q&A8), when different grades or compositions of a substance are manufactured or imported, these grades shall be reported separately in section 1.2. In case of well-defined multi-constituent substances, the same main constituents (≥10%) shall be present in each composition.

Accordingly, the Registrant is requested to revise the compositional information in section 1.2, listing all constituents and impurities (including ortho-isomers as requested under section II.2) present in the registered substance. For each constituent, including the main constituent and any impurity, the typical, minimum and maximum concentration level shall be specified. When different grades /compositions are manufactured, the Registrant shall report separately the compositional information of each grade. ECHA underlines that only the grade(s) referring to the same substance (in this case possessing the same main constituents ≥10%) are covered by one registration. The Registrant would need to submit a separate registration for any separate substance including any other grade having different main constituents than the registered substance subject to the present decision.

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 on the ECHA website.

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.

2. Timeline for submitting the information

In his comments to the draft decision, the Registrant requested to prolong the timeline for submission of the requested information from 3 to 6 months. The Registrant indicated that for the registered substance being a complex multiconstituent substance more time would be required in order to generate relevant analytical data. However, ECHA considers that the 3 months deadline starting from the decision becoming effective is appropriate to comply with the information request and it is also in line with the deadlines given to other registrants for similar cases. Therefore, ECHA has not modified the deadline of the decision in response to this comment.

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.

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