ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003375-74-06/F Helsinki, 11 December 2013

**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 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after 20 June 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 20 May 2013 ECHA received comments from the Registrant.

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

On 20 June 2013 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, a Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 26 July 2013 ECHA notified the Registrant of the proposal 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 amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and did not amend the draft decision.

On 5 August 2013 ECHA referred the draft decision to the Member State Committee.

On 13 August the Registrant submitted comments on the proposal for amendment. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee on 25-27 September 2013, a unanimous agreement of the Member State Committee on the draft decision as modified (Sections II and III) at the meeting was reached on 26 September 2013. 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 and 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. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7).

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 **11 March 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.

### 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 and 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 and 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, InChI, SMILES notation and structural formula 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 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.

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 IUPAC name currently specified in the IUCLID dossier with the name "tris(methylphenyl)phosphate". ECHA observes that such a name describes a substance including all possible isomers of tris(methylphenyl)phosphate and does not correspond to a substance including a limited number of isomers of tris(methylphenyl)phosphate. ECHA calls the Registrant's attention on the fact that the name included in the "IUPAC name" field 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 $\geq$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.

In addition, the Registrant provided for the registered substance the name "Reaction mass of 3-Methylphenyl di-4-methylphenyl Phosphate and 4-Methylphenyl di-3-methylphenyl Phosphate and tris(3-methylphenyl)phosphate", which he intends to include in the "synonyms" field of the IUCLID dossier. The Registrant also indicated that the registered substance could still correspond to the substance identified by EC entry 215-548-8 (and in analogy to CAS 1330-78-5) that is currently specified in the IUCLID dossier. As described above, EC entry 215-548-8 (and CAS entry 1330-78-5) coincides to a substance including all possible isomers of tris(methylphenyl)phosphate.

ECHA notes that, in accordance with section 5 ("Criteria for checking if substances are the same") of the Guidance, a substance including all possible isomers is not regarded equal to a substance with only a subset of the possible isomers (*c.f.* the example of Difluorotoluenes provided in the Guidance). Based on the compositional information provided, the registered substance consists of a subset of all possible isomeric constituents of tris(3-methylphenyl)phosphate. In line with the Guidance such subset cannot be regarded as equal to the substance identified by EC 215-548-8. As a consequence the EC (and CAS) entry currently specified in the registration dossier is not appropriately identifying the substance that is actually manufactured.

In addition, ECHA notes that the name proposed by the registrant as a "synonym" corresponds exactly to the registered substance as described in the dossier, which mainly consists of the three isomers 3-Methylphenyl di-4-methylphenyl Phosphate, 4-Methylphenyl di-3-methylphenyl Phosphate and tris(3-methylphenyl)phosphate. As a consequence the proposed name does not constitute a mere "synonym". Contrary to the name currently reported, this name describes adequately the registered substance.

Accordingly, the Registrant is requested to clarify the identity of the substance by providing consistent name and other identifiers of the substance. More concretely, in order to ensure consistency between the reported composition and the identifiers of the substance, ECHA considers that the name "Reaction mass of 3-Methylphenyl di-4-methylphenyl Phosphate and 4-Methylphenyl di-3-methylphenyl Phosphate and tris(3-methylphenyl)phosphate" shall replace the name currently included in the "IUPAC name" field in section 1.1 of the registration dossier.

The appropriate chemical (IUPAC) name and other identifiers, including EC and CAS, shall be included in the corresponding fields of IUCLID section 1.1.
Concerning the modification of CAS identifier, if none of the existing CAS entry 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 anti-wear additives [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 above-mentioned proposal for amendment, the Registrant stated that the registered substance "*does not contain ortho-isomers as these are present only as trace amounts in the starting material*". The Registrant in addition provided information on the specifications of such starting material which indicate that the ortho-cresol isomer, which is the precursor of the ortho-isomers in the final product, is present at a maximum concentration level of [redacted]%.

ECHA notes that such information indicates that the presence of ortho-isomers cannot be excluded from the composition of the registered substance. In addition, the concentration value indicated by the Registrant is referring to the starting material used for manufacturing the substance and is not sufficient as such to conclude on the concentration levels of the ortho-isomers that may be present in 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, and also as specified by the Registrant in his comments, "*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. This observation is further supported by the fact that the current concentration values specified in the dossier do not cover 100% of the composition. [redacted] In line with the Guidance, the composition of well-defined substance should be covered up to 100%. For multi-constituent substances, the sum of typical concentrations for main constituents (≥ 10%) and impurities (< 10%) shall be 100%.

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 clarify 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. *Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)*

In line with the above observations (under b.), ECHA notes that the Registrant did not provide sufficient information on the analytical methods used for the identification and quantification of the different constituents present in the composition of the registered substance, which is a requirement of Annex VI, section 2.3.7. of the REACH Regulation. Without making the analytical methods available it will not be possible to verify the compositional information provided.

More specifically ECHA notes that the Registrant provided information on the relative integral area values of constituents or groups of constituents as part of a chromatographic analysis. Such analytical data, however, do not include information on how the Registrant derived the concentration levels of the ortho-isomers of tris(methylphenyl) phosphate that cannot be excluded from the composition of the registered substance (see above b.).

The Registrant is accordingly requested to provide a description of the methods used to determine the constituents required to be reported in the composition of the registered substance. Such information may be derived not only on the basis of direct analytical techniques carried out directly on a sample of the registered substance or on a derivatisation product of the registered substance, but also by means of calculations carried out on the basis of the composition of the starting material and considering the manufacturing process steps which can affect the concentrations of the impurities present in the 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.

## 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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Director of Evaluation