EUROPEAN CHEMICALS AGENCY

~~HIGHLY RESTRICTED~~

Decision number: CCH-D-0000003886-61-05/F Helsinki, 24 June 2014

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

For 2-ethylhexyl diphenyl phosphate, CAS No 1241-94-7 (EC No 214-987-2), 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 2-ethylhexyl diphenyl phosphate, CAS No 1241-94-7 (EC No 214-987-2), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI). Following receipt of a proposal for amendment from a Member State Competent Authority regarding chronic aquatic toxicity classification, ECHA stresses that it has checked the information provided by the Registrant and other joint registrants for compliance with the requirements of Annexes VII to IX relating to aquatic toxicity.

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 31 May 2013.

On 29 July 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.

By 29 August 2013 the Registrant did not provide any comments on the draft decision to ECHA.

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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 5 December 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.

The ECHA Secretariat reviewed the proposal 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 proposal(s) 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 proposal(s) 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

Pursuant to Articles 41(1)(a), 41(3), 10(a)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Title I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- the hazard classification of the registered substance for acute aquatic toxicity Category 1 and chronic aquatic toxicity Category 2 based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a), 4.1.0. (b)(ii) and 4.1.4), as specified in section III below. In the alternative, the Registrant is required to provide reasons why no such classification is given.

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 **1 October 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 requirement. The scope of the present decision is limited to classification and labelling for aquatic toxicity (Annex VI, Sections 4.1 and 4.2 of the REACH Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the technical dossier and the attachment to the technical dossier:
Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In addition, for each entry, reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes the following:

The technical dossier includes aquatic acute toxicity studies indicating an $L(E)_{50}$ equal to or lower than 1 mg/l which is considered reliable by the Registrant (Klimisch score 1 or 2). However, the Registrant has not classified the substance as Aquatic Acute Hazard Category 1 and used the resulting hazard statement "H400: Very toxic to aquatic life", which would be in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. and 4.1.4 of the CLP Regulation).

Moreover, a Member State Competent Authority proposed to amend the decision and request the hazard classification of the registered substance for Chronic Aquatic Hazard Category 1. The request was based on adequate chronic toxicity data available in the technical dossier only for two trophic levels (Fish and *Daphnia*, no growth rate-based NOEC for algae study available) and the BCF being 500.

ECHA notes that the NOEC value for Algae study reported in the technical dossier is based on cell number (cell number = biomass (growth)) of 72 µg/L. However, following evaluation of the technical dossier and its attachment, ECHA notes that the Registrant has indicated adequate chronic toxicity data available for three trophic levels including a growth rate-based percent inhibition of 14.6 indicating an NOEC (NOErC) value for algae of < 52 µg/L. The BCF is > 500.

Pursuant to the Guidance on the Application of the CLP Criteria Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures (Version 4.0, November 2013), classification shall be based on NOErC [= NOEC (growth rate)] provided that the control growth is exponential (greater than a factor of 16). This endpoint is preferred because it is not dependent on the test design, whereas the endpoint biomass (growth) inhibition depends on both, growth rate of the test species as well as test duration and other elements of test design

Besides, the technical dossier and its attachment includes aquatic chronic toxicity studies indicating a NOErC or equivalent value from the Algae study equal to or lower than 0.1 mg/l. The Registrant considers the result reliable (Klimisch score 1 or 2). The Registrant also consideres the substance as rapidly degradable by the Registrant.

Regardless of these results, the Registrant has not classified the substance as Aquatic Chronic Hazard Category 2 and used the resulting hazard statement "H411: Very toxic to aquatic life with long lasting effects", which would be in line with the criteria set out in Part 4 of Annex 1 of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. (b)(ii) and 4.1.4 of the CLP Regulation). Furthermore, the technical dossier does not contain scientifically justified reasons relating to why the substance has not been classified in accordance with the available study/studies.

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP Regulation as specified above and is consistent with the data on aquatic toxicity available in the registration dossier. The Registrant shall also provide resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a), 4.1.0. (b)(ii) and 4.1.4). In the alternative, the Registrant is required to provide reasons why no such classification is given.

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

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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