ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 27 April 2018

Addressee: [redacted]

Decision number: CCH-D-2114408319-50-01/F
Substance name: Tetraphenyl m-phenylene bis(phosphate)
EC number: 260-830-6
CAS number: 57583-54-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28/05/2015
Registered tonnage band: Over 1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 (1) (a), (c) and (3) of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Classification and labelling (Annex VI, Section 4.): apply classification and labelling on the registered substance for acute and chronic aquatic hazards or provide a justification for not classifying;**

2. **Identification of PNEC (Annex I, Section 3.3.1.): derive PNECs for freshwater, marine water, freshwater sediment, marine sediment, and soil using the study giving rise to the highest concern according to Annex I, Section 3.1.5 *or* provide a detailed justification for not using the study giving rise to the highest concern;**

3. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for the environment and human health: should the substance be classified as per point 1, generate an exposure assessment for identified uses and perform a risk characterisation accordingly.**

You have to submit the requested information in an updated registration dossier by **5 November 2018**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex I and VI to the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. Hazard classification and resulting hazard label for acute and chronic aquatic hazards (Annex VI, 4.)

Pursuant to Article 10(a)(iv) of the REACH Regulation the technical dossier shall contain information on classification and labelling of the substance as specified in Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (hereinafter CLP Regulation).

Annex VI, Section 4.1. of the REACH Regulation 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, the scientifically justified 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 the relevant available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation and the specific concentration limits and M-factors, where applicable, resulting from the application of Article 10 of the CLP Regulation (Annex VI, Sections 4.2 and 4.3 of the REACH Regulation).

ECHA notes that your dossier does not contain any classification for acute or chronic aquatic hazards. As a reason for not classifying the registered substance for aquatic hazards, you have indicated that the data were "conclusive but not sufficient for classification".

However, ECHA considers that the registered substance should be classified for acute and chronic aquatic hazards, for the reasons detailed below.

ECHA notes that you have reported in your dossier the following study results:

- 48h-EC50 of 0.76 mg/L on *Daphnia magna,* based on measured concentrations ([redacted] 1999)[2],
- In the study of [redacted] 2006[3] on algae (*Pseudokirchnerella subcapitata*), two water accommodated fractions (WAF) with loading rates of 100 mg/L and 10 mg/L were prepared. After 72h, a reduction of the growth rate compared to the controls was measured for the loading rate of 100 mg/L. No effects were observed for the loading rate of 10 mg/L, which corresponded to a measured concentration of 0.009 mg/L. Based on measured concentrations, a 72h-NOEC of 0.009 mg/L can therefore be derived from this study.

Both studies are flagged as reliable in the registration dossier.
ECHA also notes that the registered substance is readily biodegradable.

2 [redacted]

Pursuant to Title I and II of the CLP Regulation and the criteria set out in Part 4 of its Annex I, (Tables 4.1.0. (a) and/or (b) and 4.1.4), substances for which 48h-EC50 for crustacea are ≤ 1 mg/L shall be classified as 'category acute 1' for acute (short-term) aquatic hazard, with hazard statement "H400: Very toxic to aquatic life".

In addition, substances that are rapidly degradable and for which chronic NOEC or ECx for fish or crustacea or algae are ≤ 0.01 mg/L shall be classified as 'category chronic 1' for long-term aquatic hazard, with hazard statement "H410: Very toxic to aquatic life with long lasting effects".

In your comments on the draft decsion, following the procedure set out in Article 50(1) of the REACH Regulation, you have considered that both the 48h-EC50 of 0.76 mg/L on *Daphnia magna* from the study of [redacted] 1999 and the 72h-NOEC of 0.009 mg/L on algae from the study of [redacted] 2006 should not be regarded as reliable any longer.

In particular, you have explained that the *Daphnia* study of [redacted] 1999 was performed above the water solubility level of the registered substance.

As for the algae study of [redacted] 2006, you have indicated that the measured concentrations were not for the registered substance, but for triphenyl phosphate (TPP), an impurity which has a much higher water solubility limit than the registered substance and therefore on which analytical measurements were easier to conduct. You have also indicated that the concentration of TPP in the WAF decreased during the 72 hours of testing from 0.018 mg/L to 0 for the 10 mg/L WAF. You have explained that the probable reason for this decrease was the hydrolysis of TPP. You have indicated that the hydrolysis half-life of TPP is 3 d at 25 °C and pH 9. Algae tend to increase pH levels to a level around >9 during the test, so hydrolysis of TPP may have been significant in that study. By comparison, the hydrolysis half-life of the registered substance is 21 d at 20 °C and pH 9. The NOEC of 0.009 mg/L was then calculated as the average value of 0.018 mg/L and 0. However, based on your comments, ECHA acknowledges that you do not consider anymore that this value reflects the toxicity level of the registered substance.

Consequently, you have proposed to perform the algae study (OECD 201) and the *Daphnia* study (OECD 202) using improved analytical methods for direct analysis of the registered substance.

ECHA agrees with your comments on the draft decision that the results of the 48h-EC50 of 0.76 mg/L on Daphnia magna from the study of [redacted] 1999 and the 72h-NOEC of 0.009 mg/L on algae from the study of [redacted] 2006 do not reflect the toxicity level of the registered substance:

- The *Daphnia* study of [redacted] 1999 was indeed performed above the water solubility limit of the registered substance, and even though the 48h-EC50 of 0.76 mg/L is expressed based on measured concentrations, it is not clear how these concentrations were measured (based on the registered substance itself or on TPP).

- ECHA also agrees that the 72h-NOEC of 0.009 mg/L on algae from the study of [redacted] 2006 is not reliable. Indeed, ECHA acknowledges that the concentration of the registered substance in the test medium should not be extrapolated from the concentration of TPP.

Firstly, the water solubility of TPP is higher by three orders of magnitudes than the water solubility of the registered substance, so the concentration of TPP in the WAF was arguably higher than the concentrations of the other constituents. Secondly, TPP likely hydrolysed faster than the registered substance during this test.

Whilst you have proposed to perform the algae study (OECD 201) and the *Daphnia* study (OECD 202) using improved analytical methods for direct analysis of the registered substance. ECHA notes that based on the available valid information in the technical dossier which this draft decision is based on, both studies are flagged as reliable and therefore the registered substance requires a classification. You are reminded that this decision does not take into account any updates submitted after notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

According to Title I and II of the CLP Regulation and the criteria set out in Part 4 of its Annex I, (Tables 4.1.0. (a) and/or (b) and 4.1.4), substances that are rapidly degradable and for which chronic NOEC or ECx for fish or crustacea or algae are > 0.01 mg/L to ≤ 0.1 mg/L shall be classified as 'category chronic 2' for long-term aquatic hazard, with hazard statement "H411: Toxic to aquatic life with long lasting effects". Therefore, based on the available valid information in the technical dossier on the registered substance which this decision was based on, 21d-NOEC of 0.021 mg/L from the long-term study on *Daphnia magna* of [redacted] 2014, the registered substance needs to be classified at least as 'category chronic 2'.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, you are requested to provide adequate hazard classification and the resulting hazard label for acute and chronic aquatic hazards for the registered substance subject to the present decision taking into account the available valid information above. In the alternative, you are required to provide scientifically justified reasons based on factual evidence why such classification is not warranted. ECHA reminds you that also for a differentiation of a hazard class, you shall provide scientifically justified reasons.

2. Identification of PNEC and risk characterisation (Annex I, Sections 3.3.1. and 6.)

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

In particular, Article 14(3)(c) and Annex I, Section 3. of the REACH Regulation requires to establish a Predicted No-Effect Concentration (PNEC) for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

Annex I, Section 3.1.5. of the REACH Regulation requires that the study or studies giving rise to the highest concern shall normally be used to derive the PNEC and a robust study summary shall be prepared for that study or studies and included in the technical dossier. In addition, Annex I, Section 3.1.5. requires that if a study giving rise to the highest concern is not used, then this shall be fully justified.

You have provided study summaries for the following aquatic toxicity tests:

- [redacted] 2006a: a water-accommodated fraction (WAF) with a loading rate of 100 mg/L was used for this short-term toxicity test on fish (*Danio rerio*). No effects were observed.
- [redacted] 1996: a 96h-LC50 of 12.37 mg/L on fish (*Danio rerio*) was calculated based on nominal concentrations. Measured test concentrations were in the range of [redacted] of the nominal concentrations. The LC50 value corresponding to measured concentrations was not calculated. An emulsifier (Tween 80) was used for preparing the stock solutions.
- [redacted] 2006b: two WAF with loading rates of 100 mg/L and 10 mg/L were prepared for this short-term toxicity test on aquatic invertebrates (*Daphnia magna*). No effects were observed.
- [redacted] 1999: a 48h-EC50 of 0.76 mg/L on aquatic invertebrates (*Daphnia magna*) was calculated based on measured concentrations. A solvent (dimethylformamide) was used for preparing the stock solutions.
- [redacted] 2001: a 21d-NOEC of 0.021 mg/L on aquatic invertebrates (*Daphnia magna*) was derived based on measured concentrations. A solvent (dimethylformamide) was used for preparing the stock solutions.
- [redacted] 2014: a 21d-NOEC of 0.021 mg/L on aquatic invertebrates (*Daphnia magna*) was derived based on measured concentrations. It was the highest concentration tested in this study. A solvent (dimethylformamide) was used for preparing the stock solutions.
- [redacted] 2006: two WAF with loading rates of 100 mg/L and 10 mg/L were prepared for this study on algae (*Pseudokirchnerella subcapitata*). After 72h, a reduction of the growth rate compared to the controls was measured for the loading rate of 100 mg/L. No effects were observed for the loading rate of 10 mg/L, which corresponded to a measured concentration of 0.009 mg/L. Based on measured concentrations, a 72h-NOEC of 0.009 mg/L can therefore be derived from this study.
- [redacted] 1995: a 72h-NOEC of 24.3 mg/L on algae (*Pseudokirchnerella subcapitata*) was derived based on nominal concentrations. The value corresponding to measured concentrations could not be calculated. An emulsifier (Tween 80) was used for preparing the stock solutions.

All these studies are reliable as you indicated yourself in the dossier.

You have used the 21d-NOEC of 0.021 mg/L from the long-term studies on *Daphnia magna* of [redacted] 2001 or [redacted] 2014 as a starting point to derive the PNEC values for freshwater and marine water. However, ECHA notes that a lower NOEC (0.009 mg/L based on measured concentrations) can be calculated from the study of [redacted] 2006 on algae. Therefore, ECHA considers that you have not used the study giving rise to the highest concern to derive the PNECs for freshwater and marine water. ECHA notes that you did not provide a justification for it.

ECHA further notes that you have calculated PNECs for soil and for freshwater and marine sediments by applying the Equilibrium Partitioning Method (EPM). This method takes PNEC value for water as input. Therefore, if PNECs have to be derived for freshwater and for marine water, then PNECs for soil, freshwater sediment and marine sediment have also to be revised accordingly.

In your comments on the draft decsion, following the procedure set out in Article 50(1) of the REACH Regulation, you have considered that the 72h-NOEC of 0.009 mg/L on algae from the study of [redacted] 2006 should not be regarded as reliable any longer for the reasons explained above, in Section 1 of this Appendix. Consequently, you have proposed to perform this study (according to test guideline OECD 201) as well as the *Daphnia* study (according to test guideline OECD 202), on the registered substance.

ECHA agrees that the result on algae from the study of [redacted] 2006 does not reflect the toxicity level of the registered substance. However, as indicated above whilst you have proposed to perform the algae study (OECD 201) and the Daphnia study (OECD 202) using improved analytical methods for direct analysis of the registered substance. ECHA notes, that based on the available valid information in the technical dossier which this draft decision is based on, both studies are flagged as reliable and therefore the registered substance still requires a classification. You are reminded that this decision does not take into account any updates submitted after notification of the draft decision to you. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to derive PNECs for freshwater, marine water, freshwater sediment, marine sediment and soil using available valid results of the study giving rise to the highest concern, according to Annex I, Section 3.1.5 of the REACH Regulation *or* provide a full justification for not using the study giving rise to the highest concern.

3. Exposure assessment and risk characterisation for the environment and human health (Annex I, Sections 5. and 6.)

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

The CSA shall cover 1) human health hazard assessment, 2) human health hazard assessment of physicochemical properties, 3) environmental hazard assessment and 4) PBT and vPvB assessment.

Pursuant to Article 14(4) and Annex I, Section 0.6.3. of the REACH Regulation, if as a result from these steps, the substance meets the criteria for any hazard classes or categories set out in Annex I to the CLP Regulation, or is assessed to be a PBT or vPvB, then the CSA shall also include the additional steps: an exposure assessment, including generation of exposure scenario(s) and exposure estimation, and a risk characterisation. The additional steps of the CSA shall be carried out in accordance with Sections 5 (for the exposure assessment) and 6 (for the risk characterisation) of Annex I of the REACH Regulation.

ECHA notes that your CSR contains no exposure assessment and neither risk characterisation for human health nor for the environment. However, as ECHA outlined in Section 1 of this Appendix, based on current available information in the technical dossier, the registered substance needs to be classified for aquatic hazards, unless you provide scientifically justified reasons based on factual evidence why no such classification is given.

In the expected case of classification, your CSA shall include an exposure assessment and a risk characterisation as required by Article 14(4) and Annex I, Section 0.6.3. of the REACH Regulation.

Furthermore, according to Annex I, Section 5.0., the objective of the exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4 of chapter 0.6 of Annex I.

As further outlined in ECHA Guidance on information requirements and chemical assessment, Part B, chapter B.8.1 Scope of Exposure Assessment (version 2.1, December 2011), such identified hazards necessitating exposure assessment include both "*hazards for which there are classification criteria and there is information to establish that the substance meets the criteria*" and "*hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified*".

Moreover, the above mentioned guidance specifies further (in Section 8.4.1.3) that "*if the criteria for classification of the identified hazard are not met, it may still be possible to derive a DNEL and thus an exposure assessment will be required*".

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate an exposure assessment and a risk characterisation for all identified hazards, both for the environment and human health for all identified uses in the dossier, in case the substance is classified.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 30 August 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the request(s).

Following consideration of your comments, ECHA notes that in the request, Identification of PNEC (Annex I, Section 3.3.1.), the word "revise" PNECs for freshwater, marine water….." was replaced by the word "derive" PNECs for freshwater, marine water. ECHA considers that the word "derive" describes more accurately, the scope of the task of this request. In addition, Appendix 1 has been modified, accordingly.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.