Helsinki, 24 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465597-33-01/F
Substance name: Tris(2-ethylhexyl) phosphate
EC number: 201-116-6
CAS number: 78-42-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27/03/2018
Registered tonnage band: Over 1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD TG 218) using the registered substance,**

   OR

   Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test method: Sediment-water Chironomid life-cycle toxicity test using spiked water or spiked sediment, OECD TG 233) using the registered substance.

You have to submit the requested information in an updated registration dossier by **4 May 2020**. You also have to update the chemical safety report, where relevant.

The reasons for 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.

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 Wim De Coen, Head of Unit, Hazard Assessment.

[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

The decision of ECHA is based on the examination of the testing proposals submitted by you.

1. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on sediment organisms. You mention the Sediment-water Chironomid toxicity test using spiked sediment (OECD TG 218) in IUCLID in the endpoint study title, and within the endpoint study information, in the sections "Material & Method" and "Justification for type of information", the Sediment-water Chironomid life-cycle toxicity test using spiked water or spiked sediment (OECD TG 233) is indicated. You included the following justification: "*In accordance with Column 2 of REACH Annex X, Section 9.5.1 and ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7.B, this substance is anticipated to sorb to sediment to a significant extent. ECHA considers that registrants should provide a PNECsediment for non-classified and non-PBT substances that meet this criteria even where no effects at the limit of water solubility are seen in aquatic species that would facilitate sediment hazard assessment using equilibrium partitioning theory. Additionally, equilibrium partitioning theory can not be used for substances that are highly insoluble and for which no effects are observed in aquatic studies. Therefore at least one sediment toxicity study has to be performed, in this instance the registrant proposes that a sediment-water Chironomid life-cycle toxicity test using spiked sediment is performed (OECD 233).*"

ECHA agrees with your conclusions. The registered substance is adsorptive (predicted Log Koc 6.3 and 6.4), has a low water solubility (0.14 µg/L) and widespread and consumer uses are reported in the dossier. Therefore, ECHA considers that exposure to sediment cannot be excluded.

ECHA considers that the proposed studies are appropriate to further investigate long-term toxicity to sediment organisms (Annex X, Section 9.5.1. of the REACH Regulation).

Spiking the sediment is recommended for industrial chemicals with continuous and intermittent releases, while spiking the water phase is recommended to simulate pesticide spray drift event and other type of exposure (e.g. chemical spill) (ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7b, R.7.8.9.1 (June 2017, Version 4.0)). ECHA notes that in the technical dossier manufacture, formulation, industrial, proffesional and consumer uses are reported, with several uses reported [redacted] from which only one identified use may have a spray drift event [redacted]. Therefore, ECHA considers the sediment spike route to be the most appropriate study to fulfil the requirements of Annex IX, Section 9.5.1.

ECHA further notes that the registered substance composition includes the impurity [redacted] This impurity has been included in the Annex III inventory[2] due to being suspected hazardous to the aquatic environment. Therefore, the test material used for testing should include this impurity.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision:

- Sediment-water Chironomid toxicity using spiked sediment (test method: OECD TG 218)
  OR
- Sediment-water Chironomid life-cycle toxicity test using spiked sediment (test method: OECD TG 233)].

Notes for your consideration

Due to the registered substance properties, you are advised to consider the feeding recommendations given in the OECD test guidelines 218 and 233. The guidelines recommend that when testing strongly adsorbing substances (typically with log Kow > 5) in order to cover the dietary exposure food should be added to the formulated sediment before the stabilisation period (paragraph 31 of OECD test guidelines 218 or 233).

[2] https://echa.europa.eu/substance-information/-/substanceinfo/100.030.362

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 27 March 2018.

This decision does not take into account any updates after **17 October 2018**, 30 calendar days after the end of the commenting period.

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 did not receive any comments by the end of the commenting period.

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 decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the 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 the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.