Helsinki, 24 July 2017

Addressee: [redacted]

Decision number: CCH-D-2114367253-50-01/F
Substance name: REACTION MASS OF P-T-BUTYLPHENYLDIPHENYL PHOSPHATE AND BIS(P-T-BUTYLPHENYL)PHENYL PHOSPHATE AND TRIPHENYL PHOSPHATE
EC number: 700-990-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 09.07.2015
Registered tonnage band: [redacted]

DECISION ON A COMPLIANCE CHECK

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

1. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **31 January 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.

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] 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.

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EUROPEAN CHEMICALS AGENCY

Appendix 1: Reasons

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at [redacted] must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study records for the key study *Toxicity of S-154 to the freshwater alga Selenastrum capricornutum* and the supporting study *Toxicity of seven potential polychlorinated biphenyl substitutes to algae and aquatic invertebrates*. However, those studies do not provide the information required by Annex VII, Section 9.1.2., because they are not reliable as explained in the following.

ECHA observes that the effect levels for the studies above are based on nominal concentrations. However, in the studies provided on plants there is neither analytical monitoring nor data confirming that exposure to nominal concentrations is maintained during the tests. In addition, the analytical verification of the test concentrations in the toxicity studies with fish and aquatic invertebrates showed a decrease of concentrations of the registered substance in the testing system. Consequently, ECHA considers that the substance has potential for being lost from the test system during aquatic toxicity testing. Thus, in order to gather adequate results for the purpose of classification/labelling and risk assessment, analytical verification of exposure concentrations of the substance (and its degradation products, if indicated) is necessary for the aquatic toxicity testing, especially for the static test design. Therefore, ECHA considers that the results of both such studies reported in the registration dossier are not adequate for the purpose of classification/labelling and risk assessment.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

ECHA acknowledges that in your comments to the draft decision according to Article 50(1) of the REACH Regulation you confirmed the need to perform requested Algae growth inhibition study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

Notes for your consideration

Due to the low solubility of the substance in water and observed losses of the substance from test solutions you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test and for calculation and expression of the result of the test.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 18 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a Simulation testing on ultimate degradation in water (Annex IX, Section 9.2.1.2.), identification of the degradation products (Annex IX, Section 9.2.3.) and PBT/vPvB assessment (Annex I, section 4 and Annex XIII). As these requests are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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 28 November 2016.

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 requests and the deadline.

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.

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.