EUROPEAN CHEMICALS AGENCY

Helsinki, 27 April 2017

[redacted]

Decision number: TPE-D-2114359935-34-01/F
Substance name: Phenol, isopropylated, phosphate (3:1)
EC number: 273-066-3
CAS number: 68937-41-7
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 12 August 2015

**FOLLOW-UP EVALUATION DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION**

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has examined the information you submitted as a response to decision TPE-D-0000002325-80-06/F ('the original decision').

**ECHA concludes that after the expiry of the deadline set in the testing proposal decision, your registration does not comply with the information requirements in Annex X, 9.4.4. to the REACH Regulation.**

Therefore, ECHA communicates this decision[1] to the Member State competent authority (MSCA) and national enforcement authority (NEA) of your country for enforcement action. The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. 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, shall 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[2] by Ofelia Bercaru, Head of Unit E3

[1] The decision, once adopted, will be sent to the Member State competent authority and the national enforcement authority for enforcement action.
[2] 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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**Appendix 1: Reasons**

This decision is necessary after the follow-up evaluation according to Article 42(1) of the REACH Regulation, because in your updated registration as a response to the decision TPE-D-0000002325-80-06/F ('the original decision') you have provided substantial new experimental data which ECHA has assessed for compliance with the information requirements of the REACH Regulation and the outcome is that your registration still does not comply with the information requirements addressed in the original decision.

**Terrestrial Invertebrates (Annex X, 9.4.4)**

In the original decision you were requested to submit information derived with the registered substance for Long-term toxicity to terrestrial invertebrates.

In the updated registration subject to follow-up evaluation, you have submitted the results of a short-term toxicity study on terrestrial invertebrates according to OECD guideline 207 (Earthworm, Acute toxicity test) with the registered substance.

The conducted short-term study was transparently reported in the dossier and all the validity criteria were met. However, the short-term study cannot fulfil the information requirement related to long term toxicity to terrestrial invertebrates since it does not cover the relevant parameters as per the OECD 222 test guideline i.e. the effects of long-term (4 weeks) exposure on adult earthworm mortality and growth, and the effects of long-term (8 weeks) exposure on the reproductive output of the exposed earthworms.

In the updated registration dossier subject to follow-up evaluation, you have also submitted the results of valid long-term toxicity studies on *Daphnia magna* (according OECD TG 211) and fish (according to OECD TG 210) as requested in the original decision. Based on these results the substance can be concluded to be very toxic to aquatic organisms.

Furthermore, in the updated registration dossier subject to follow-up evaluation, you have submitted results of a valid OECD TG 218 long-term toxicity study on the sediment dwelling invertebrate species, *Chironomus riparius*, as requested in the original decision. Based on these results, the substance can be concluded to pose long-term hazardous effects on sediment invertebrates.

After taking into account all newly updated information for the relevant environmental endpoints, such as hazardous effects seen at the short-term earthworm test, very high aquatic toxicity observed in the new *Daphnia* and fish long-term toxicity tests and hazardous effects seen already at the lowest treatment level in the long-term sediment toxicity test with the sediment dwelling invertebrate *C. riparius*, a risk for the terrestrial compartment cannot be excluded and the long-term earthworm study is still considered necessary. Furthermore, taking into account very high aquatic toxicity, the high adsorption potential (reported log Kow 4.92-5.17) and potentially high persistency (reported not to be readily biodegradable), the substance falls into soil hazard category 4, where the long-term terrestrial toxicity testing according to standard information requirements of Annex X is required.

Hence, the short term toxicity study on terrestrial invertebrates according to OECD guideline 207 does not fulfil the information requirement related to long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4) on its own or together with the other newly submitted information. Therefore, the request in the original decision was not met, and the following endpoint remains incompliant: information on Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222 or *Enchytraeid* reproduction test, OECD 220, with the registered substance.

## Appendix 2: Procedural history

The original decision was issued on 16 April 2013. You were required to update the registration with the requested information by 16 April 2015.

You updated your registration on 12 August 2015.

The follow-up evaluation was initiated on 12 September 2016.

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

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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

ECHA received proposals for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendments.

ECHA referred the draft decision to the Member State Committee.

You provided comments only on the draft decision. Your comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-53 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

## Appendix 3: Further information, observations and technical guidance

1. For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date of receipt of the draft follow-up evaluation decision.

2. The Article 42(2) notification for the original testing proposal decision is on hold until all information requested in this compliance check decision has been received.

3. ECHA recommends that you contact your Member State's authorities to agree on when and how to bring the registration in compliance.