EUROPEAN CHEMICALS AGENCY

Helsinki, 29 August 2017

Addressee:
[redacted]

Decision number: TPE-D-2114368824-38-01/F
Substance name: Calcium phosphinate
EC number: 232-190-8
CAS number: 7789-79-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10/06/2016
Registered tonnage band: 100-1000

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 testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) using 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 an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **5 June 2018**. 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 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

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

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation.

Your registration dossier contains a long-term toxicity study on *Daphnia magna* with aluminium hypophosphite ([redacted] 2011)[2], but which you have disregarded. ECHA acknowledges that this study has shortcomings and agrees that it could be regarded as invalid. Consequently, ECHA considers that your registration dossier does not contain valid information for "Long-term toxicity testing on aquatic invertebrates".

In accordance with column 2 of Section 9.1. of Annex IX of the REACH Regulation, you shall propose this test "*if the chemical safety assessment according to Annex I* [of the REACH Regulation] *indicates the need to investigate further the effects on aquatic organisms*". ECHA has identified some deficiencies in your chemical safety assessment:

- You have considered your substance to be readily biodegradable for your assessment. Biodegradability tests are designed to assess the use of the test substance as a carbon source to microorganisms. However the registered substance is inorganic therefore biodegradability tests are not sensible. Still, you have not demonstrated that your substance will not persist in the environment. The hypophosphite ion is not naturally present in the environment. You have provided no evidence that it will transform to other forms of phosphorus that are naturally present in the environment. Therefore, by default it shall be considered persistent for your assessment. Consequently, ECHA considers that your exposure assessment and therefore your risk assessment are not correct.

- You have provided the result of a Fish, Prolonged Toxicity Test: 14-Day Study according to OECD 204 study ([redacted] 2011)[3]. For your assessment, you have regarded this study as a long-term study on fish. This is not correct. This test cannot be considered a suitable long-term test. It is a prolonged acute study to examine fish mortality. Besides, this test guideline is obsolete as it is no longer available since 2 April 2014 following an OECD Council decision. Consequently, ECHA considers that the PNEC you have derived is not adequate and therefore that your risk assessment is not correct.

Therefore ECHA considers that the available information in your chemical safety assessment does not demonstrate the safe use of the registered substance and does not rule out long-term effects to aquatic organisms. Pursuant to column 2 of Section 9.1. of Annex IX of the REACH Regulation, ECHA concludes that you need to investigate further the long-term effects on aquatic organisms.

[2] [redacted] (2011). [redacted]

[3] [redacted] (2011). [redacted]

The information on "Long-term toxicity testing on aquatic invertebrates" 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 aquatic invertebrates *Daphnia magna* reproduction test, EU C.20/OECD TG 211. ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

Notes for your consideration

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

As explained above, you shall also correct the deficiencies identified by ECHA in your current chemical safety assessment, in particular with regard to the degradation rates assumed for the exposure assessment, and the PNEC.

If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, you shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If you come to the conclusion that no further investigation of effects on aquatic organisms is required, you shall update your technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 10 June 2016.

This decision does not take into account any updates after **18 May 2017**, 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 carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, 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.