~~Confidential~~

Helsinki, 10 March 2022

Addressees
Registrants of Dimelamine_pyrophosphate_JS listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
29/03/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Diphosphoric acid, compound with 1,3,5-triazine-2,4,6-triamine (1:2)
EC number: 236-860-0
CAS number: 13518-93-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***19 December 2022***.

The requested information must be generated using the Substance unless otherwise specified.

A. Information required from the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33./OECD TG 222)

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annexes IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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.

Approved[1] under the authority of Mike Rasenberg, Director of 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 A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Long-term toxicity testing on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Based on the information in your registration dossier, the substance is considered as not readily biodegradable. In your technical dossier, you acknowledge that "*Experimental studies investigating biodegradation of diphosphoric acid, compound with 1,3,5-triamine (1:2) in soil are not available*". You further explain that "*The substance will dissociate in aqueous environments under environmentally relevant conditions forming melamine and pyrophosphate ions*" and you report a half-life for melamine (i.e. the organic part of the salt) of 2-3 years in soil.

Therefore, the Substance is concluded to be highly persistent in soil and information on long-term toxicity on terrestrial organisms must be provided.

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an Earthworm Reproduction Test (test method: OECD TG 222) with the following justification: "*The substance is not readily biodegradable, has a low potential for adsorption and a low aquatic toxicity. According to the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance (ECHA, 2017), the substance is assigned to soil hazard category 3. Thus a confirmatory long-term soil toxicity testing is proposed*".

You have also provided an adaptation under Annex XI, Section 3 ('Substance-tailored exposure-driven testing') with the following justification: "*The substance is not intended to be directly applied to soil. The direct and indirect release rates to soil during manufacture, formulation, industrial use and wide dispersive uses of the substance are negligible. The environmental exposure assessment for the substance indicates no risk for the terrestrial compartment (all RCR< 1; please refer to Chapter 9 and 10 of the Chemical Safety Report for detailed information)*".

ECHA has assessed the proposed adaptation and identified the following issue:

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(a) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a PNEC can be derived from available data. Where no soil toxicity data are available, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity, which rely on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment. The use of the EPM method, however, provides only an uncertain assessment of risk and,

while it can be used to modify the standard data-set requirements of Annex IX and X, it cannot alone be used to obviate the need for further information under these Annexes.

iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

(b) For substances that are not included in articles, it must be demonstrated for all relevant scenarios that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply throughout the life cycle

(c) For substances incorporated in articles with no intended releases, the following conditions are met:

i. the substance is not released during its life cycle and,

ii. the likelihood that workers and the general public are exposed to the substance under normal or reasonable foreseeable conditions is negligible, and

iii. the substance is handled according to the conditions as set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

With regard point a) above, for substance belonging to hazard category 3, Table R.7.11—2 of ECHA Guidance R7c specifies that the results of a confirmatory long-term toxicity test on terrestrial organisms is needed to confirm the outcome of the screening assessment using the EPM. As specified in your justification for the testing proposal, "*the substance is assigned to soil hazard category 3".* However, your registration dossier does not include such information.

With regard point b) and c) above, you have not provided any justification that the Substance is handled under strictly controlled conditions.

To conclude, the information on an adaptation of the information in your dossier does not meet any of the conditions for an exposure based adaptation specified in Annex XI, Section 3.2. Your adaptation is therefore rejected.

ECHA therefore agrees that an appropriate study on long-term toxicity to terrestrial invertebrates is needed.

1.2. Test selection and study specifications

The proposed Earthworm Reproduction Test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test material must contain that constituent/ impurity.

2. Information on the Test material needed in the updated dossier
   - You must report the composition of the Test material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 December 2019.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

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

ECHA did not receive any comments within 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 adopted the decision under Article 51(3) of REACH.

Appendix D: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[6]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[7]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.