EUROPEAN CHEMICALS AGENCY

Helsinki, 9 June 2020

Addressees
Registrants of ATMP-H_acid_JS listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
18 February 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Nitrilotrimethylenetris(phosphonic acid)
EC number: 229-146-5
CAS number: 6419-19-8

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***14 June 2021***.

A. Requirements applicable to all the Registrants subject to Annex X of REACH

- Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4; test method: OECD TG 222) using the analogue substance ATMP xNa/ [nitrilotris(methylene)] trisphosphonic acid, sodium salt (EC 243-900-0, CAS 20592-85-2)

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier. You have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information they are required to submit to fulfil the information requirements for their registration.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

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

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 Christel Schilliger-Musset, 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 for the requirement applicable to all the Registrants subject to Annex X of REACH

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

1. Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.)

Effects on terrestrial organisms is a standard information requirement in Annex X, Section 9.4.4.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD TG 222) with an analogue substance ATMP xNa/ [nitrilotris(methylene)]trisphosphonic acid, sodium salt (EC 243-900-0, CAS 20592-85-2). You justify your testing proposal by arguing that soil hazard category 3 (ECHA Guidance R.7c, Table R.7.11-2) applies to the Substance. According to the screening assessment for soil hazard category 3 substances, you have calculated a PNECsoil from the aquatic data on the basis of Equilibrium Partitioning Method (EPM) and submitted the above testing proposal for a confirmatory long-term toxicity test to terrestrial invertebrates.

ECHA agrees that the Substance falls into soil hazard category 3 as it has a high potential to adsorb to soil due to high polarity and metal-chelating capacity leading to irreversible binding onto the mineral fraction of soil. Therefore ECHA agrees that the proposed test is appropriate to fulfil the information requirement of Annex X, Section 9.4.4.

ECHA understands that you seek to adapt this information requirement according to Annex XI, Section 1.5. to REACH. In your testing proposal, as well as in the read-across document provided as part of your Chemical Safety Report, and data matrix provided in the technical dossier (IUCLID section 13), you provide the following justification:

- the Substance (ATMP) and the analogue substance (ATMP xNa) are similar in molecular structure with only difference that the analogue substance is the ionised form of the Substance.
- the environmental fate of both substances is governed by the high polarity and by the very similar metal-chelating capacity leading to irreversible binding onto the mineral fraction of soils and sediments.
- in dilute aqueous conditions of defined pH the analogue substance (ATMP xNa) will behave no differently to the Substance (ATMP).
- both substances have similar low environmental toxicity in all available studies.

ECHA agrees that the provided information generally supports your hypothesis. Therefore, based on the information currently available, ECHA considers that your adaptation appears to meet the general rule for adaptation of Annex XI; Section 1.5.

Under Article 40(3)(a) of the REACH Regulation you are requested to carry out the proposed test using the analogue substance ATMP xNa/[nitrilotris(methylene)] trisphosphonic acid, sodium salt (EC 243-900-0, CAS 20592-85-2).

Appendix B: Procedural history

ECHA received your registration containing the testing proposal for examination on 18 February 2019.

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

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 adopted the decision under Article 51(3) of REACH.

Appendix C: Observations and technical guidance

1. This testing proposal examination decision does not prevent ECHA from initiating compliance checks at a later stage on the registrations present.

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(s).

3. Test guidelines, GLP requirements and reporting

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

   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.

   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: 'How to report robust study summaries'[2].

4. Test material

   Selection of the test material

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

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

5. List of references of the ECHA Guidance and other guidance/ reference documents[4]

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 in this decision.

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

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.

OECD Guidance documents
Guidance Document on aqueous –phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.

[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

Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.