Helsinki, 9 December 2019

Addressees
Registrants of ATMP-N-oxide-5K_salt_JS listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
12 September 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Pentapotassium({[(hydroxyphosphinato)methyl](phosphonatomethyl) nitroryl}methyl)phosphonate
EC number: 700-903-6
CAS number: 255830-15-0

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 ***15 December 2020***.

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

1. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; 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 request

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.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII-IX to REACH, if you have registered a substance at 100-1000 tpa;

The Appendix on general considerations addresses common arguments that are applicable throughout the present decision while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The testing material used to perform the required studies shall be selected and reported in accordance with the specifications prescribed in Appendix Observations and technical guidance.

The data sharing obligations set up in REACH require the registrants to ensure that the costs of sharing information are determined in a fair, transparent and non-discriminatory way.

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

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 Schillinger-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 requirements applicable to all the Registrants subject to Annex IX of REACH

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

1. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)**

Effects on terrestrial organisms is a standard information requirement in Annex IX, Section 9.4 to REACH. Column 2 of Section 9.4 of Annex IX specifies that long-term toxicity testing must be considered instead of short-term testing, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

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 IX, Section 9.4.1., column 2.

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 supplemental read-across document and data matrix provided in the technical dossier (IUCLID section 13), you provide the following justification:

- the Substance (ATMP N-oxide) and the analogue substance (ATMP) are similar in molecular structure with the only difference that the Substance has a non-reactive amine N-oxide group.
- 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.
- the Substance (ATMP N-oxide) is expected to be slightly more polar and generally less toxic than the analogue 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. However, we emphasise that any final determination on the validity of your read-across adaptation will only be possible when the information on requested studies will be available in the dossier.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the Earthworm reproduction test (OECD TG 222) using the analogue substance ATMP xNa/[nitrilotris(methylene)] trisphosphonic acid, sodium salt (EC) (EC 243-900-0, CAS 20592-85-2).

Appendix B: Procedural history

ECHA received your registration containing the testing proposal for examination on 12 September 2018.

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 the 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 took the decision according to Article 51(3) of the REACH Regulation.

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

   According to 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.

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

   According to 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 an analogue substance 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. When testing an analogue substance, the test material selected must be representative of the specified analogue substance. The selection of test material shall must support the read-across prediction, as presented in the read-across justification document.

While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint(s) to be assessed. For example, if a constituent/ impurity of the analogue substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

Technical reporting of an analogue substance test material

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values.

Further instructions on what needs to be reported for the analogue substance test material composition are available in Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (Chapter 4.4).

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

5. List of references of the ECHA Guidance documents[3]

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)[4]

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.

[3] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[4] 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]