

Helsinki, 19 November 2021

Addressees

Registrants of Joint Submission P101 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision

20/11/2020

Registered substance subject to this decision, hereafter 'the Substance'

Substance name: N-(2-nitrophenyl)phosphoric triamide

EC number: 477-690-9

CAS number: NS

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 **28 November 2022**.

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

Information required from the Registrants subject to Annex IX of REACH

1. Dissociation constant (Annex IX, Section 7.16.; test method OECD TG 112);
2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)
3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

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

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>.

Approved¹ 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 to request information required under Annex IX of REACH

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

1. Dissociation constant

Dissociation constant is an information requirement under Annex IX to REACH (Section 7.16).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Dissociation constant in water test (test method: OECD TG 112) on the Substance with the following justification:

"An experimental determination of the dissociation constant is only necessary if a significant dissociation in the pH range of 5 - 9 can be expected through a (QSAR) calculation. The dissociation of 2-NPT was calculated with the program MarvinSketch 6.1.0. The following results were obtained: pKa: 6,01 and pKb: - 0,59. Since a relevant dissociation of the molecule is to be expected in the environmentally relevant pH range, a test is necessary".

ECHA agrees that an appropriate study on Dissociation constant is needed.

1.2. Test selection and study specifications

The proposed Dissociation constants in water test (test method: OECD TG 112) is appropriate to cover the information requirement for Dissociation constant (ECHA Guidance R.7.1.17.3.).

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.

2. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on fish only. In case of data gap for long-term toxicity testing on aquatic invertebrates, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1. Information provided to fulfil the information requirement

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates. Instead, you have provided the following justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2:

- *"The available data are adequate for classification and labelling purposes";*
- *"In acute toxicity experiments, no adverse effects up to the highest tested concentration (e.g. 100 mg/l) were observed".*
- *"Furthermore, the water solubility of the substance is 1394 mg/l. As no risk to aquatic life was identified in the chemical safety assessment already prepared for the tonnage band 10 to 100 t/a (Risk Characterisation Ratio [REDACTED]), no concern for aquatic*

invertebrates is identified”.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to invertebrates under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Therefore, you have not demonstrated that this information can be omitted. Your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

2.2. Test selection and study specifications

The *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

2.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

3. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

3.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) with the following justification: *“The Board of Appeal published a decision on a compliance check on 04.05.2020 and stated: „Based on its wording, context and objectives, Column 2 of Section 9.1. of Annex IX must be interpreted as meaning that registrants are required to submit information on a further study than one of the three listed in Column 1 of Section 9.1.6. of Annex IX, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do.” Regarding this clarification on the testing requirement for long-term toxicity to fish the test cannot be waived based on column 2 adaptations. Therefore, as a minimum, one study on long-term toxicity on fish has to be proposed.”*

Your registration dossier does not include any information on long-term toxicity on fish.

ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity on fish. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that an appropriate study on long-term toxicity on fish is needed.

3.2. Test selection and study specifications

The proposed Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

3.3. 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 summaries².

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 dossiers³.

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 8 February 2021.

ECHA held a third party consultation for the testing proposal(s) from 18 March 2021 until 3 May 2021. ECHA did not receive information from third parties.

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 Guidance⁴ and other supporting documentsEvaluation 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 documents⁷

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.