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Helsinki, 02 November 2023

Addressee(s)
Registrant(s) of JS_methylphosphonic-acid as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
02/06/2022

Registered substance subject to this decision ("the Substance")
Substance name: Methylphosphonic acid
EC number/List number: 213-607-2

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***11 November 2024***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202);
2. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201).

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 for the request(s)

Contents

Reasons common to several requests

0.1. Read-across adaptations rejected

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5.:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.).

2 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

3 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Predictions for ecotoxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance from information obtained from the source substance Methylphosphonic acid, compound with amidinourea (1:1) (MPAAU), EC 282-758-4.

7 You provide the following reasoning for the prediction of ecotoxicological properties:

8 "*Both MPA and MPAAU have comparable physical-chemical properties and are therefore supposed to behave similarly in biological systems hence supporting the approach for read-across from the source chemical, MPAAU to the target chemical, MPA. Both chemicals are phosphonate derivatives. The target chemical is the free methyl phosphonic acid which is processed with dicyandiamide to receive an equimolar reaction product representing the source chemical MPAAU. In a dried form MPAAU is a salt consisting of the methyl phosphonic anion and the cationic amidinourea. Both chemicals, as the free acid as well as the reaction product are strong hydrophilic substances with a high solubility in water.*"

9 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products since the source substance dissociates into the Substance and a non-common compound. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

10 We agree that a reliable prediction of the properties under consideration of the Substance can be derived on the basis of your read-across hypothesis.

0.1.2. Adaptations rejected due to issues with the specific source data

11 However, we have identified the following issue(s) with the prediction(s) of ecotoxicological properties:

12 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;

(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

13 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement sections 1 and 2. Therefore, no reliable predictions can be made for these information requirements.

0.2. Your comments on the read-across approach

14 In the comments on the draft decision, you inquire further information how to conduct this study because

15 - the Substance is corrosive (pH: 1) and cannot be tested as such but needs to be neutralised before application, and

16 - ECHA rejected the read-across approach to the data generated on the neutralised reaction product (i.e. the source substance).

17 By contrast, and as clarified in Sections 0.1 and Sections 1.2 and 2.2, we agree that the properties of the Substance could be predicted using data on the source substance. The reasons to reject the read-across adaptation are only related to the available study records and specifically the reliability of this data on the source substance.

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

18 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

1.1. Information provided

19 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a short-term toxicity study on *Daphnia* (1995) with the source substance Methylphosphonic acid, compound with amidinourea (1:1), EC 282-758-4 (MPAAU).

1.2. Assessment of the information provided

20 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected because ECHA has identified the following endpoint specific issue(s):

21 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 202. Therefore, the following specifications must be met:

22 Validity criteria

a) the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);

b) the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test.

23 Characterisation of exposure

c) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

24 In study (i):

25 Validity criteria

a) the percentage of immobilised daphnids at the end of the test in the control was not provided;

b) the dissolved oxygen concentration in controls and/or test vessels at the end of the test was not provided.

26 Characterisation of exposure

c) no analytical monitoring of exposure was conducted.

27 Based on the above, the information on validity criteria of the OECD TG 202 is missing. On that basis it is not possible to independently assess the reliability and confirm the validity

of the study results. Furthermore, there are critical methodological deficiencies resulting in the rejection of the study. More specifically, the concentrations of the test material throughout the test duration were not analytically verified (monitored).

28 On this basis, the specifications of OECD TG 202 are not met.

29 The study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG. Therefore your adaptation is rejected and the information requirement is not fulfilled.

1.3. Study design and test specifications

30 The Substance is difficult to test due to the ionisable properties (the reported water solubility >20 g/L and the reported dissociation constants of 2.2 and 7.7 indicate that the Substance easily dissociates in aqueous solution). The OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in the OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in the OECD TG 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

31 In the comments on the draft decision, you agreed to perform the requested study.

2. Growth inhibition study aquatic plants

32 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

33 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) Growth inhibition study on algae (2012) with the source substance Methylphosphonic acid, compound with amidinourea (1:1), EC 282-758-4 (MPAAU).

2.2. Assessment of the information provided

34 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected because ECHA has identified the following endpoint specific issue(s):

35 Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case the OECD TG 201. Therefore, the following specifications must be met:

36 Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;

b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

c) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;

d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Pseudokirchneriella subcapitata* .

37 Characterisation of exposure

e) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

f) the concentrations of the test material are measured at least at the beginning and end of the test:

- at the highest, and
- at the lowest test concentration, and
- at a concentration around the expected EC_{50}.

38 Reporting of the methodology and results

g) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);

h) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

39 In study (i):

40 Validity criteria

The information on the above validity criteria a)-d) is missing.

41 Characterisation of exposure

e) the analytical monitoring is indicated, however, the results of analytical monitoring of exposure concentrations throughout the test duration arenot reported;

f) there is no information if the concentrations of the test material were analytically verified at the beginning and at the end of the test.

42 Reporting of the methodology and results

g) on the test design, you have not specified the number of replicates, the number of test concentrations and the geometric progression used;

h) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

43 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the information on validity criteria of the OECD TG 201 is missing. Furthermore, there is no information whether the concentrations of the test material were analytically verified at the beginning and at the end of the test. In addition, the results of algal biomass determined in each flask at least daily during the test period

are not reported. On that basis it is not possible to independently assess the reliability and if the validity criteria of the OECD TG 201 are met for the study.

44 On this basis, the specifications of OECD TG 201 are not met.

45 The study submitted in your adaptation, as currently reported in your dossier, does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG. Therefore your adaptation is rejected and the information requirement is not fulfilled.

2.3. Study design and test specifications

46 The OECD TG 201 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' in section 1.3 above.

47 In the comments on the draft decision, you agreed to perform the requested study.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

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

The compliance check was initiated on 02 May 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

ECHA took into account your comments and did not amend the request(s).

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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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.

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

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With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).