~~Confidential~~

Helsinki, 27 April 2023

Addressee(s)
Registrant(s) of JS_939402-02-5 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/08/2022

Registered substance subject to this decision ("the Substance")
Substance name: Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters
EC number/List number: 700-485-5

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 ***2 February 2026***.

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

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

1. Long-term toxicity testing on aquatic invertebrates, also requested below (triggered by Annex VII, Section 9.1.1., Column 2).

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

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211);

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

4. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.25/OECD TG 309).

The reasons for the request(s) are explained in Appendix 1.

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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the

standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

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Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

2 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required.

3 In the provided OECD TG 105 (2010), the saturation concentration of the Substance in water was determined to be <0.1 mg/L. Further information on the water solubility of the Substance is available from the provided aquatic toxicity studies. For example, the saturation concentration of the Substance in the short-term daphnia study was determined to be 0.421 mg/L (Short-term daphnia toxicity, key study, 2010).

4 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

1.2. Information requirement not fulfilled

5 The information provided, its assessment and the specifications of the study design are addressed under request 2.

Reasons related to the information under Annex IX of REACH

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Information provided

7 You have provided a long-term toxicity study on *Daphnia magna* (2011) with the Substance.

2.2. Assessment of the information provided

8 To fulfil the information requirement, a study must comply with the OECD TG 211 and the specifications of the OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) Young female *Daphnia*, aged less than 24 hours at the start of the test, are used;

b) Parental animals are not first brood progeny.

Characterisation of exposure

c) It must be demonstrated that concentrations were consistently maintained within 80-120% of the nominal or measured initial values over the exposure duration. Results can be based on nominal (or measured initial values) only when there is evidence that the concentration of the substance has been satisfactorily maintained within 80-120% of the nominal concentration (or measured initial concentration) throughout the test.

Test Design

d) A continuous flow through exposure system is used if exposure concentrations cannot be maintained within 80-120% of nominal or measured initial values in a semi-static exposure system with a renewal frequency of 24 hours.

9 In the study provided:

Technical specifications impacting the sensitivity/reliability of the test

a) The test was conducted on Daphnia which were stated to be ‘adults’ at the start of the study with no age provided;

b) No information is provided to confirm that the parental animals were not first brood progeny.

Characterisation of exposure

c) Exposure concentrations were not consistently maintained within 80-120% of the nominal or measured initial values over the exposure duration.

10 Test Design

d) You have used a semi-static test design with a renewal frequency of 24 hours and provide analytical monitoring results which show that exposure

concentrations were not consistently maintained within 80-120% of nominal or measured initial values.

11 Based on the above:

a) You do not provide sufficient information on the test organisms to confirm that all key technical specifications of the OECD TG 211 have been met. The daphnia should have been <24 hours old at the start of the test however you do not provide the age of the daphnia used. The age of the daphnia is a key factor in the sensitivity of the test. It is not possible to confirm that the daphnia were <24h old at test start hence the test cannot be considered reliable.

b) Furthermore, no information on whether the daphnia used were first brood progeny is provided. The use of first brood progeny can impact the reliability of the study. It is not possible to verify that this key test specification is met hence the test cannot be considered reliable.

c) The Substance is difficult to test based on low water solubility (e.g. <0.1 mg/L based on OECD TG 105) and adsorptive properties (Log Kow 6.58) and there are critical methodological deficiencies resulting in the rejection of the study results. Since the substance is difficult to test difficulties maintaining stable test concentrations can be expected and nominal values may not be representative of actual exposure concentrations. The analytical monitoring results provided show that exposure concentrations were not consistently maintained at all test concentrations during the test. You have based effect levels on nominal values but the analytical monitoring results show that exposures were not maintained between 80-120% of the nominal concentrations or measured initial concentrations. The results based on nominal values are therefore considered unreliable.

d) A continuous flow-through exposure system should be used when a static-renewal exposure system with renewals every 24 hours is incapable of maintaining exposure concentrations. You have used a semi-static test design with a renewal frequency of 24 hours whereas this test design was not adequate to maintain exposure concentrations during the test.

12 Taken together, based on the above deficiencies the hazard could be underestimated.

13 On this basis, the specifications of the OECD TG 211 are not met. Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

14 The Substance is difficult to test due to the low water solubility (e.g. <0.1 mg/L based on the OECD TG 105) and adsorptive properties (Log K_{ow} 6.58). The OECD TG 211 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 211. 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.

15 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

16 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

a) use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);

b) provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);

c) prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

3. Simulation testing on ultimate degradation in surface water

17 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

3.1. Information provided

18 You have adapted this information requirement by using Column 2 of Annex IX, Sections 9.2 and 9.2.1.2. To support the adaptation, you have provided following justification: '*In accordance with points 9.2.1.2, Column 2, Annex IX, further degradation testing shall only be considered if the Chemical Safety Assessment indicates the need to investigate further the degradation of the substance. Furthermore, the study does not need to be conducted if the substance is highly insoluble in water and if direct and indirect exposure of surface water and sediment is unlikely. The substance was found to be highly insoluble in water in the submitted water solubility study, and direct and indirect exposure of sediment is considered unlikely. Testing is therefore not required*.'

3.2. Assessment of the information provided

3.2.1. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

19 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

20 Therefore, your adaption based on Annex IX, Section 9.2., Column 2 is rejected.

3.2.2. The provided adaptation does not meet the criteria of annex IX, Section 9.2.1.2., Column 2

21 Under Annex IX, Section 9.2.1.2., Column 2, first indent, the study can be omitted in case the Substance is highly insoluble.

22 There is no cut off value in the REACH Regulation for the term *'highly insoluble'*. What is most important is what can be assessed in a study, i.e., it is necessary to demonstrate that it is not reasonably possible to develop an analytical method with sufficient sensitivity to meet the test guideline requirements taking into account the specific technical limitations of the OECD TG 309 which include, in particular:

a) for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and

b) the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

23 Consequently, a substance has an insolubility too high for conducting a simulation testing on ultimate degradation in surface water in accordance with OECD TG 309 if the LOQ of a sensitive analytical method is not at least ten times lower to the water solubility of the substance.

24 In the provided OECD TG 105 study (2010) the water solubility of the Substance was determined to be <0.1 mg/L. Further information on the water solubility of the Substance is available from the provided aquatic toxicity studies. For example, the saturation concentration of the Substance in the short-term aquatic toxicity tests ranged from 0.193 mg/L (Short-term fish toxicity, key study, 2010) to 0.421 mg/L (Short-term daphnia toxicity, key study, 2010).

25 You report analytical methods for the Substance having the following limits of quantification (LOQs): 0.00044 mg/L (Short-term fish toxicity key study, 2010) and 0.0024 mg/L (Short-term daphnia toxicity, key study, 2010).

26 In support for your adaptation, you do not provide any arguments regarding technical limitations relevant to the conduct of the OECD TG 309.

27 You also state that the direct and indirect exposure of sediments is unlikely.

28 The information in the dossier indicates that analytical methods with LOQs of 0.00044 mg/L to 0.0024 mg/L are available for the Substance, which are more than ten times lower than the water solubility of the Substance. A sensitive analytical method is therefore available providing evidence that the surface water simulation study can be conducted.

29 Based on the information in the dossier the Substance is not highly insoluble in water, and conduct of the surface water simulation study is technically feasible.

30 Furthermore, the likelihood of direct or indirect exposure of sediments is not an adaptation possibility under 9.2.1.2 column 2 for the surface water simulation study.

31 Therefore, the adaptation is rejected and the information requirement is not fulfilled.

3.3. Study design and test specifications

32 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(2) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(3) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

33 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

34 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

35 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

36 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

4. Identification of degradation products

37 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

4.1. Information provided

38 You have provided some information on the identity of the hydrolysis products, but no information on the identity of further transformation/biodegradation products for the Substance. Therefore, the information requirement is not fulfilled.

4.2. Study design and test specifications

39 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

40 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified

transformation/degradation products must be considered in the CSA including PBT assessment.

41 You must obtain this information from the degradation study requested in request 3.

42 To determine the degradation rate of the Substance, the requested study according to the OECD TG 309 (request 3) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

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

The information requirement for long-term toxicity to fish (Annex IX, Section 9.1.6.) is not addressed in this decision. It may be addressed in a separate decision once the information from the studies requested in the present decisions is provided.

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 30 June 2022.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 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 did not receive any comments during 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 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]
[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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU)

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

440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

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).

2. General recommendations for conducting and reporting new tests

2.2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

a) the "known constituents approach" (by assessing specific constituents), or

b) the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or

c) the "whole substance approach", or

d) various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.