~~Confidential~~

Helsinki, 03 June 2024

Addressees
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
25 November 2013

Registered substance subject to this decision ("the Substance")
Substance name: 6-oxo- 6H–Dibenz[c, e] [1, 2] oxaphosphorin 6-alkyl derivative
EC/List number: 700-929-8

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 ***10 June 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 (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211)

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

3. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; test method: EU C.47./OECD TG 210)

The reasons for the requests 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 addressee of the decision and his corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requests
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 requests

Contents

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 In the provided key study OECD TG 105 (2011) and the supporting study OECD 105 (2012), the saturation concentration of the Substance in water was determined to be 0.326 ± 0.010 mg/L (CV = 3.1%) and 1.01 ± 0.12 mg/L (CV = 12%), respectively. Furthermore, in the available ecotoxicological studies, all tested measured concentrations were well below 1mg/L.

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

1.2. Information provided

4 You have provided a long term invertebrate study (2013) performed with the Substance.

1.3. Assessment of the information provided

1.3.1. The provided study does not meet the specifications of the test guidelines

5 To fulfil the information requirement, a study must comply with the OECD TG 211 and the specification(s) of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The Substance is difficult to test as it has low solubility (< 1 mg/L) and it hydrolyses fast (DT50 at 25 °C of 25.5 and 0.418 hours at pH 7 and 9, respectively). Therefore, the following specifications must be met:

Additional requirements applicable to difficult to test substances

a) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

   1) an analytical method validation report demonstrating that the analytical method is appropriate, and

   2) information on the saturation concentrations of the test material in water and in the test solution, and

   3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

b) the efficacy of the separation method is assessed (e.g. by checking for the Tyndall effect or by any other appropriate means);

Reporting of the methodology and results

c) the test medium fulfils the following condition(s): total organic carbon (TOC) ≤ 2 mg/L, dissolved oxygen concentration ≥ 3 mg/L, hardness ≥ 140 mg/L (as CaCO3),

pH between 6 and 9;

d) the full record of the daily production of living offspring during the test in each replicate is provided;

e) adequate information on the results of the analytical determination of exposure concentrations is provided.

6 In the provided study*:*

Additional requirements applicable to difficult to test substances

a) no evidence was provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and

2) information on the saturation concentrations of the test material in water and in the test solution, and

3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

b) the efficacy of the separation method is not assessed using appropriate method

Reporting of the methodology and results

c) TOC was not reported;

d) the full record of the daily production of living offspring during the test in each replicate is not provided;

e) on the analytical method, measured concentrations at each sampling time were not provided.

7 Based on the above,

- the Substance is difficult to test since it is poorly water soluble and hydrolysable and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not provided information on the saturation concentrations of the test material in the test medium used to conduct the study, nor is there any information about a preliminary experiment demonstrating that the test solution preparation method and separation technique is adequate to maximize the concentration of the test material in solution. Therefore, you have not demonstrated that the test organisms were satisfactorily exposed to the test material.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability, since the full record of the daily production of living offspring during the test in each replicate, TOC and measured concentrations at each sampling time were not provided.

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

9 In the comments to the draft decision, you indicate your intentions to provide additional information to address the issue identified above regarding demonstration that "*all reasonable efforts have been taken to achieve a saturation concentration*". You indicate your intentions to rely on "*additional data from the existing report, or by generating new*

data" to provide this in a future update of the registration dossier. No additional information was provided in the comments to the draft decision.

10 As indicated in the comments, this strategy relies essentially on data which is not available for ECHA's assessment or yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

1.4. Study design

11 OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23.

12 The Substance is difficult to test as it has low solubility (< 1 mg/L) and it hydrolyses fast (DT50 at 25 °C of 25.5 and 0.418 hours at pH 7 and 9, respectively). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in 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 tested 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 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 tested substance in the test solution.

13 Considering the hydrolysis half-life, it is important to consider the relative toxicities of the parent test chemical and its hydrolysis products to determine which is more relevant for the aquatic toxicity hazard assessment i.e. the more toxic one should be tested (OECD GD 23, para. 82, second bullet, and 86).

14 Based on the currently available information it is not possible to conclude yet on the relative toxicities of the parent and the hydrolysis products for aquatic toxicity testing.

15 Therefore, before conducting the requested toxicity study, you must determine the relative toxicity between the parent Substance and its degradation product(s), e.g. by preliminary toxicity test(s) or QSARs. Based on that information, you must choose whether the parent Substance or its hydrolysis product(s) are more relevant for the aquatic toxicity hazard assessment and used for testing.

16 Appropriate test design and test media preparation methods are required in accordance with section 7.3 of OECD GD 23, to ensure that the concentrations of the parent Substance (or its hydrolysis products) are maximised and maintained in the test solution. In all cases you must monitor the test concentration(s) of the Substance and/or hydrolysis product(s) throughout the exposure duration and report the results.

17 If testing on the parent Substance is relevant, it may not be possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)). In this case, you must express the effect concentration based on measured values as described in OECD TG 211 (OECD GD 23).

2. Growth inhibition study aquatic plants

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

2.1. Information provided

19 You have provided a growth inhibition study on aquatic algae (2011) performed with the Substance.

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the specifications of the test guidelines

20 To fulfil the information requirement, a study must comply with OECD TG 201 and the specification(s) of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The Substance is difficult to test as it has low solubility (< 1 mg/L) and it hydrolyses fast (DT50 at 25 °C of 25.5 and 0.418 hours at pH 7 and 9, respectively). Therefore, the following specifications must be met:

Additional requirements applicable to difficult to test substances

a) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and

2) information on the saturation concentrations of the test material in water and in the test solution, and

3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

b) the efficacy of the separation method is assessed (e.g. by checking for the Tyndall effect or by any other appropriate means);

Reporting of the methodology and results

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

d) adequate information on the results of the analytical determination of exposure concentrations is provided;

21 In the provided study:

Additional requirements applicable to difficult to test substances

a) no evidence was provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate, and

2) information on the saturation concentrations of the test material in water and in the test solution, and

3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

b) the efficacy of the separation method is not assessed using appropriate method

Reporting of the methodology and results

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

d) the results of the analytically determined exposure concentrations are not provided for each measured time point;

22 Based on the above,

- the Substance is difficult to test since it is poorly water soluble and hydrolysable and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of an estimate of the saturation concentration of the test material in the specific test medium and of the results of a preliminary solubility experiment, you have not demonstrated that all reasonable efforts have been taken to maximize the exposure to the test material. Furthermore, you have provided no information on the separation technique so it is proven that it did not cause losses of the test substance from the test medium. Therefore, you have not demonstrated that the test organisms were satisfactorily exposed to the test material.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, measured concentrations at each sampling time and results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form were not provided.

23 On this basis, the specifications of OECD TG 201 are not met and the information requirement is not fulfilled.

24 In the comments to the draft decision, you indicate your intention to provide additional information to address the issue identified above regarding demonstration that "*all reasonable efforts have been taken to achieve a saturation concentration*". You indicate your intention to rely on "*additional data from the existing report, or by generating new data*" to provide this in a future update of the registration dossier. No additional information was provided in the comments to the draft decision.

25 As indicated in the comments, this strategy relies essentially on data which is not available for ECHA's assessment or yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

2.3. Study design

26 OECD TG 201 specifies that, for difficult to test substances, 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' under request 1.4.

Reasons related to the information under Annex VIII of REACH

3. Long-term toxicity testing on fish

27 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

3.1. Triggering of the information requirement

28 As already explained in request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

29 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

3.2. Information provided

3.3. Assessment of the information provided

3.3.1. The OECD TG 204 is not a valid test guideline to meet this information requirement

30 To fulfil the information requirement, a study must be a long-term fish test. Guidance on IRs and CSA, Section R.7.8.4.1. specifies that only studies in which sensitive life-stages (juveniles, eggs and larvae) are exposed can be regarded as long-term fish tests.

31 Your registration dossier provides an OECD TG 204 study in which only juveniles were exposed to the test material.

32 This study does not provide information on the toxicity of the test material to all relevant sensitive life-stages (i.e. juveniles, eggs and larvae). OECD TG 204 only provides information on prolonged acute toxicity and, based on the above, it does not qualify as a long-term fish test. Therefore, this information is rejected.

33 In the comments to the draft decision, you claim that "*it is questionable whether further testing on vertebrates will improve the hazard and risk assessment of this substance*" considering lack of effects seen in all aquatic species tested.

34 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex VII, Section 9.1.2., Column 2.

35 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex VII, Section 9.1.2., Column 2.

36 Therefore, you have not demonstrated that this information can be omitted.

37 On this basis, you remain responsible to comply with this decision by the set deadline.

3.4. Study design

38 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

39 OECD TG 210 specifies that, for difficult to test substances, 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' under request 1.4.

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 (2023).
***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.

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

The compliance check was initiated on 05 June 2023.

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

Deadline to provide the requested information

In the comments to the draft decision, you requested an extension of the deadline to provide information from 24 to 30 months from the date of adoption of the decision.

You state that the deadline provided in the draft decision is "*sufficient for the conduct of the test and receipt of report from the CRO*" however, you argue that it does not consider for the time required to "*for the dossier update (generation of robust summaries and CSR adaptation)*".

The deadline set by ECHA in the draft decision already considers the procedural time needed to contract the study to a Contract Research Organisation and to prepare a dossier update based on the results of the study, including any considerations to update the CSR and to update the dossier based on the requirements in the CLP Regulation.

ECHA took into account your comments and did not amend the deadline.

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 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

(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 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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