~~Confidential~~

Helsinki, 05 January 2023

Addressee
Registrant of JS_107-66-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
13/01/2022

Registered substance subject to this decision ("the Substance")
Substance name: Dibutyl hydrogen phosphate
EC/List number: 203-509-8

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)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***13 January 2025***.

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

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

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

The reasons for the decision(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 its 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 decision
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 decision

Contents

Reasons for the decision(s) related to the information under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for a Daphnia magna reproduction test (test method: EU C.20/OECD TG 211).

3 ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

1.2. Test selection and study specifications

4 The proposed 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 (Guidance on IRs and CSA, Section R.7.8.4.1.).

5 The Substance is difficult to test due to the surface-active properties (Surface tension of 52.73 mN/m in OECD TG 115). 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 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 Substance in the test solutions.

1.3. Outcome

6 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 fish

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

2.1. Information provided to fulfil the information requirement

8 You have submitted a testing proposal for a Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210).

9 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.

10 Moreover, in your justification you indicated that: *"A testing proposal for Annex IX Long Term Fish is included in the dossier based on BoA decisions A-010-2018 and A-011-2018. The BoA in A-011/2018 came to the conclusion that registrants are required to propose long-term fish testing under Annex IX in any case, and that registrants may be required to perform / shall propose (under column 2) longer term fish toxicity tests that go beyond those described in Annex IX, column 1. According to the BoA, Annex IX (section 9.1, column 2) does not allow registrants to omit information on long term toxicity to fish under column 1".*

11 However, you further consider that the evaluation of the testing proposal should be suspended until the decision of the General Court on case T-656/20, which challenges the Board of Appeal decision A-010-2018.

12 You further refer to animal welfare reasons by referring to Para. 132 of C-471/18 P stating that: *"It follows from those general provisions, which are to be construed in the light of recital 47 of the REACH Regulation, according to which it is necessary to replace, reduce or refine testing on vertebrate animals', that a registrant has, generally and therefore especially where ECHA issues it with a decision asking it to complete its registration dossier with a study involving animal testing, not simply the possibility but the obligation to generate information obtained by means other than animal testing 'whenever possible' and to undertake such testing 'only as a last resort'."*

13 ECHA notes that acts and decisions of EU Institutions and agencies are presumed lawful until they are declared void by the EU Courts. Therefore, while the court proceedings you are referring to in your comments are pending, the relevant findings of the Board of Appeal in case A-011-2018 remain fully applicable.

14 In your comments to the draft decision, you further refer to Guidance on IRs and CSA Chapter R.7b, version 4.0 of June 2017 with a view to an adaptation based on considerations from the chemical safety assessment under Annex IX, section 9.1, Column 2. As these considerations implicate sequential testing, you request an extension of the deadline for provision of the information.

15 However, ECHA re-iterates its position on the interpretation of the applicable legal provisions and its consistent practice since the Board of Appeal's decision in cases A-010-2018 and A-011-2018. ECHA no longer considers REACH Annex IX, section 9.1, Column 2 as a basis for waiving of the standard information required under Column 1. In that regard, information on aquatic toxicity described in ECHA guidance on IRs and CSA related to REACH Annex IX, section 9.1, Column 2 as a waiver for the information requirement under Column 1 is no longer valid, as also highlighted on ECHA's website[2]. Both the information on long-term toxicity testing on aquatic invertebrates as well as the information on long-term toxicity testing on fish are standard information required under Annex IX, section 9.1, Column 1. Thus, the deadline of the decision is set based on standard practice for carrying out the OECD TG tests in question.

16 A registrant may only adapt this information requirement based on the general rules set out in Annex XI; but you did not submit any such adaptation. ECHA remarks that minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

17 Therefore, ECHA agrees that an appropriate study on long-term toxicity on fish is needed and that the testing proposal can be processed.

2.2. Test selection and study specifications

[2] See the information on "Adaptation of long-term aquatic toxicity testing under Annex IX to REACH" at https://echa.europa.eu/standard-information-requirements-recommendations.

18 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 (Guidance on IRs and CSA, Chapter R.7b, Section 7.8.4.1).

19 OECD TG 210 specifies that for substances that are difficult to test, OECD GD 23 must be followed. As already explained under Request 1., the Substance is difficult to test. Therefore, you must fulfil the requirements described under section 1.2. above, '*Test selection and study specifications*'.

2.3. Outcome

20 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 10 March 2022.

ECHA held a third party consultation for the testing proposal(s) from 10 May 2022 until 27 June 2022. ECHA did not receive information from third parties.

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

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.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 24 to 36 months from the date of adoption of the decision as you consider performing sequential long-term toxicity testing. As explained in request 2, the deadline of the decision is set based on standard practice for carrying out OECD TG tests.

On this basis, ECHA has not modified the deadline to provide the information.

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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 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[3].

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 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 dossiers[4].

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