EUROPEAN CHEMICALS AGENCY

Helsinki, 10 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465948-28-01/F
Substance name: Oxydipropyl dibenzoate
EC number: 248-258-5
CAS number: 27138-31-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27 July 2018
Registered tonnage band: Over 1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposals are accepted and you are requested to carry out:

1. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) using the registered substance.**
2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) using the registered substance.**

You have to submit the requested information in an updated registration dossier by **19 April 2021**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons for this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Hazard Assessment C4

[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

The decision of ECHA is based on the examination of the testing proposals submitted by you and scientific information submitted by third parties.

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on aquatic invertebrates *Daphnia magna* reproduction test, EU C.20/OECD TG 211 with the following justification: "*Due to the use of this substance in agricultural chemical formulations, long-term testing is requested to allow for the evaluation and identification of any potential environemntal hazard.*" ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH regulation.

ECHA notes that you have also submitted a testing proposal on a "Long-term toxicity testing on fish", which is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that fish would be substantially more sensitive than aquatic invertebrates. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, also the long-term fish study (point 2 of the present decision) needs to be conducted.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to

meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for testing the registered substance long-term toxicity testing on fish Fish, early-life stage toxicity test, OECD TG 210 with the following justification: *"Due to the use of this substance in agricultural chemical formulations, long-term testing is requested to allow for the evaluation and identification of any potential environemntal hazard."* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

As discussed in Section 1 above, the *Daphnia* study requested under Section 1 is to be conducted first. The need to conduct the long-term fish study requested here is then to be determined based on the results of the *Daphnia* study and the consequent risk assessment.

ECHA requested your considerations for alternative methods to fulfil the information requirement for long-term toxicity testing on fish. ECHA notes that 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.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: Fish, early-life stage toxicity test, OECD TG 210).

Notes for your consideration

Due to the registered substance being a multi-constituent with surface active properties, you should consult OECD Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, ENV/JM/MONO(2000)6/REV1 (OECD GD 23, second edition) and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

In addition, if you decide to use the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In general, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical specific analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

Regarding the expression of the result of the test, the above guidance document recommends that all test results are expressed in terms of measured concentrations as far as possible. In particular, the "loading rate" may be used for expressing exposures of mixtures that neither wholly dissolve nor completely form a stable dispersion or emulsion over the required test range. WAFs may be thus considered analogous to the term "nominal concentration" used for typical test substances, with all the limitations inherent to that term. As indicated in the OECD TGs 210 and 211 and OECD GD 23, when the measured concentrations do not remain within 80-120% of the nominal concentration, the effect concentrations should be determined and expressed relative to measured concentrations

(see paragraph 24 of the OECD TG 210, paragraph 50 of the OECD TG 211 and chapter 9 of the above mentioned OECD GD 23).

Therefore, it is recommended that you should first consider conducting the preliminary stability test as per above mentioned OECD GD 23. If based on that test you consider that the WAF is the only option to prepare the test solution, you should report the potential effect concentrations from the WAF test based on mean measured concentrations.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 8 June 2018.

ECHA held a third party consultation for the testing proposals from 10 August 2018 until 24 September 2018. ECHA did not receive information from third parties.

This decision does not take into account any updates after **7 December 2018**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA did not receive any comments by the end of 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 took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the requests in this decision will result in a notification to the enforcement authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

   In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.