Helsinki, 5 November 2018

Addressee: [redacted]

Decision number: TPE-D-2114449819-31-01/F
Substance name: Bisdecanoyl peroxide
EC number: 212-092-1
CAS number: 762-12-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10 April 2017
Registered tonnage band: 100-1000

DECISION ON A TESTING PROPOSAL

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

Your testing proposal is accepted and you are requested to carry out:

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 may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and an adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by ***12 May 2020***. You also have to update the chemical safety report, where relevant.

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 Kevin Pollard, Head of Unit, Evaluation E1

[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.

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 for long-term toxicity testing on fish [Fish, early-life stage toxicity test, OECD TG 210] with the following justification:

"*Two long-term toxicity studies are already available for invertebrates (OECD 211) and algae (OECD 201). The Chemical safety assessment indicates the need to further investigate the risk for the pelagic aquatic compartment. Fish is the only remaining trophic level considered under REACH and for which long-term toxicity testing has not been assessed. No datum for long-term toxicity to fish is available. According to the acute toxicity tests results, there is no evidence that fish could be expected to be less sensitive than invertebrates and/or algae at long-term. In addition, fish long-term toxicity testing is a standard information requirement under annex IX of REACh regulation EC 1907/2006. Therefore, an OECD 210 is proposed as a last resort and cannot be waived.*"

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH regulation.

You state in your justification that the Chemical Safety Assessment indicates the need to further investigate the risk for the pelagic aquatic compartment. In this regard, ECHA notes that there is no quantitative risk assessment in the CSA for the pelagic compartment. However, ECHA agrees with your further statement that there is no evidence that fish could be expected to be less sensitive than invertebrates and/or algae at long-term. ECHA also notes that the short-term toxicity data on fish are based on a test conducted with an analogue substance and hence no short-term or long-term toxicity data on fish are available in the dossier for the registered substance. ECHA further notes that due to lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in 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), is not applicable in this case and the long-term studies on both invertebrates and fish are required. As the valid long-term toxicity study on aquatic invertebrates already exists and the registered substance has a reported low water solubility, a long-term toxicity study on fish is indicated and your testing proposal is accepted.

In the comments to the draft decision you proposed first to carry out an OECD 111 hydrolysis study in order to investigate the hydrolysis rate of the parent substance and the formation of potential hydrolysis products at environmentally relevant conditions. After obtaining results of the hydrolysis study, you proposed to define the strategy for assessing

the chronic toxicity of your registered substance by either testing the parent substance or the hydrolytical degradation products. In the comments to the draft decision you also requested an extention of the deadline from 12 to 24 months. You justified this request by the additional time needed to first conduct the hydrolysis study and by your experience (supported by the documents provided by two laboratories) about the additional time needed to conduct the requested test on a difficult substance of low water solubility and the anticipated challenges in maintaining and analysing the test concentrations.

ECHA notes that you already report a valid OECD TG 111 hydrolysis study ([redacted], 2013) in your registration dossier. Based on the reported hydrolytical half-lives of 23.3 days (at pH 4, 37°C), 33.7 days (at pH 7, 25°C) and 32.2 days (at pH 9, 25°C) ECHA considers it unlikely that a potential new hydrolysis study would show hydrolysis half-lives of less than 3 days (or less than 1 hour) and therefore would have effects on the strategy for assessing the chronic aquatic toxicity of the registered substance. ECHA reminds that hydrolysis as a function of pH is a REACH Annex VIII, Section 9.2.2.1. standard information requirement and therefore you can conduct a new hydrolysis test at any time without submitting testing proposal. However, ECHA acknowledges your justification about the additional time needed to conduct the requested test on a difficult substance of low water solubility (0.12 mg/L) and the anticipated challenges in maintaining and analysing the test concentrations.

Based on above ECHA has amended the decision by extending the deadline from 12 to 18 months.

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 for which testing is proposed. ECHA has taken these considerations into account. No information was submitted by third parties.

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 (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD TG 210).

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 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 test and for calculation and expression of the result of this test.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 2 August 2017.

ECHA held a third party consultation for the testing proposals from 29 September 2017 until 13 November 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **26 February 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 took into account your comments and amended 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 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, or to otherwise fulfil the information requirements with a valid and documented adaptation, 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.