Helsinki, 15 November 2018

Addressee: [redacted]

Decision number: TPE-D-2114450032-66-01/F
Substance name: 2-Hydroxy-5-nonyl(branched)-benzaldehyde oxime
EC number: 605-717-8
CAS number: 174333-80-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 7 April 2017
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 proposal is accepted and you are requested to carry out:

1. **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 ***22 November 2019***. 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.

1. 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: *"Experimental data about the long-term toxicity of the test substance to fish is needed for the hazard assessment due to the environmental behavior (persistent) and the ecotoxicity profile (toxic at acute and chronic exposure) derived from the short-term and long-term toxicity tests already available."* ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

ECHA notes that no information on long-term toxicity of the registered substance to fish is available in the registration dossier. ECHA further notes that due to the low water solubility of the registered substance, the short-term data cannot serve as a compelling evidence to predict relative differences in species sensitivity. For this reason, the aquatic Integrated Testing Stratergy (ITS) outlined in the *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3., is not applicable and the long-term testing on both invertebrates and fish are to be conducted. ECHA points out that you have already provided information in relation to long-term toxicity to aquatic invertebrates.

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.

In addition to the testing proposal, you have submitted a study according to *ASTM. 2009. Standard guide for conducting early life-stage toxicity tests with fishes. ASTM E 1241– 05* on an analogue substance Phenol, 4-nonyl-, branched (CAS No 84852-15-3, EC No 284-325-5, hereafter the "source substance").

In your testing proposal you justify why you do not consider the data from the analogue (source) substance sufficient to fulfil the information requirement. You consider that *"This read-across approach is considered to be acceptable in terms of a worst-case scenario"* but you still wish to conduct testing with the registered substance because *"since this endpoint is relevant for environmental classification and to improve the data base for the hazard assessment of this CMR substance we propose to replace the read across by experimental data for the registered substance itself".*

ECHA acknowledges that you propose to conduct a new study with the registered substance but at the same time you consider that the read-across from the source substance is acceptable as a worst-case scenario. In this regard ECHA notes the following: In your read-across hypothesis you propose that the source substance and the main constituent of the registered substance have similar structure and functional groups, similar physico-chemical properties and environmental behaviour and fate. Furthermore, you claim that the source substance exhibit a higher aquatic toxicity compared to the registered substance and thus the prediction is considered to be a conservative approach.

ECHA considers that similarity in structure and physico-chemical properties *per se* is not sufficient to enable the prediction of ecotoxicological properties of a substance as it does not always lead to predictable or similar ecotoxicological properties. ECHA acknowledges that the data-matrix you have provided in your read-across justification indicates that the source substance may be more toxic than the registered substance. However, ECHA cannot verify the reliability of the studies with source substance nor whether the results on the source and target substances are derived from tests using comparable methods. Therefore, the data matrix provided cannot currently be used to support your read-across justification. In addition, claiming that the prediction is conservative is not *per se* sufficient to enable the prediction of ecotoxicological properties of a substance and thus a sufficient basis for predicting the properties of the registered substance.

Based on above, ECHA concludes that the data on nonylphenol, that you consider as acceptable to be used as worst case scenario, could not be used to fulfill the current information requirement for the registered substance. ECHA reminds you that for the sole purpose of classification, there is no obligation to generate new data (cf. Article 8 of the CLP Regulation) but ECHA acknowledges that you want to improve the data base for the hazard assessment. Furthermore, ECHA considers that by submitting the testing proposal you have deemed it necessary to generate long-term toxicity data for the registered substance. As indicated above, ECHA deems that the read-across is not plausible and ECHA therefore accepts your proposal to generate long-term toxicity data for the registered substance.

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).

Note for your consideration

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 ecotoxicity test(s) and for calculation and expression of the result of the test(s). In addition, you should make every effort to quantify the concentrations of the substance during the test as specificed in the section "Frequency of analytical Determinations and Measurements" of the OECD TG 210. If Water Accommodated Fraction (WAF) method is used, the method to prepare the WAF should be fully described in the test report and robust chemical analysis should be provided.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination in accordance with Article 40(1) on 7 April 2017.

ECHA held a third party consultation for the testing proposals from 22 June 2017 until 7 August 2017. ECHA did not receive information from third parties.

This decision does not take into account any updates after **5 March 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, 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.