EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 6 August 2020

Addressee: [redacted]

Decision number: TPE-D-2114514926-44-01/F
Substance name: 2-ethylhexyl benzoate
EC number: 226-641-8CAS number: 5444-75-7
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 29 October 2018

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By decision TPE-D-2114346840-50-01/F of 25 October 2016 ("the original decision") ECHA requested you to submit information by 1 November 2018 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration update specified in the header above, and concludes that

Your registration still does not comply with the following information requirement(s):

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)

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

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They may consider enforcement actions to secure the implementation of the original decision and exercise the powers reserved to them under Article 126 of Regulation No 1907/2006 (penalties for non-compliance) for the period during which the registration dossier was not compliant[1].

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, shall 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.

Approved[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] See paragraphs 61 and 114 of the judgment of 8 May of the General Court of the European Court of Justice in Case T-283/15 Esso Raffinage v. ECHA
[2] 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

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

You were requested to submit information derived with the registered substance for Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: Daphnia magna reproduction test, EU C.20/OECD 211).

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

Although not explicitly claimed, we understand that you have adapted this information requirement relying on adaptations according to Annex XI, Section 2 "testing is technically not possible" and Annex XI, Section 3 "substance-tailored exposure-driven testing".

We have assessed this information and identified the following deficiencies:

A. Adaptation according to Annex XI, Section 2

Annex XI, Section 2 specifies that testing for a specific endpoint may be omitted if it is not technically feasible to conduct a study as a consequence of the properties of the substance. Furthermore, it defines that the guidance given in the test methods referred to in Article 13(3), more specifically the technical limitations of a specific method, must always be respected. OECD TG 211 is the preferred guideline to cover this information requirement.

In your adaptation you stated that "*daphnia reproduction study*", (i.e. long-term daphnia, OECD TG 211), "*was technically unfeasible*". You report that "*concentrations were not adequately attained and maintained and immobilization and/or reduced reproduction was seen not only in treatment groups but also in surfactant controls it was decided not to perform the main study*".

You also stated that in the short-term daphnia study performed according to a semi-static test design, the measured concentrations did not remain stable. Furthermore, in the acute studies you detected and quantified the exposure concentration of the Substance using GC-FID with detection limits (LOD) of 0.004 mg/L (no information on the limit of quantification (LOQ)). For long-term daphnia study, the same analytical method was used, however LOD and LOQ are not stated in the technical dossier. Further, you consider that testing is not technically possible due to the problems in maintaining the exposure concentration within 80 % observed in the acute aquatic studies and during the aborted long-term daphnia study.

The measured concentrations of the Substance have decreased during the test in all the acute aquatic studies given in the dossier. However, it was still possible to maintain stable measured concentrations in a short-term fish study (Key, Barrett, 2001, *O. mykiss*, 96h, RL1). You have not explained in your adaptation why a similar set-up as in the short-term fish study (i.e. the same vehicle, and flow-through test system) was not considered during the aborted long-term daphnia study (an OECD TG 211, 2018). In addition, more frequent renewal of the test medium could have also been considered (as recommended in OECD TG 211, paragraph 39). Moreover, even if deviation from the nominal or measured initial concentration is greater than ± 20 per cent, a valid study could still be conducted providing that the Substance is detected at the end of the renewal period. In such cases the results can be expressed in terms of the time-

weighted mean (as outlined in OECD TG 211, paragraph 50 and Annex 6) for a long-term daphnia study. Furthermore, although you did not provide LOD and LOQ of the analytical method for the long-term daphnia study, the information provided in the acute studies show that the available method is sufficiently sensitive to detect the Substance in the test solution.

In summary, ECHA considers that you have not demonstrated that it is not technically feasible to conduct the requested study. Your adaptation under Annex XI, Section 2, is hence rejected.

In your comments to the draft decision you stated that "*We reviewed the previous attempts with the test house who now conclude that a WAF study with daily media exchange would be a possible adaptation to the method*". This information supports ECHA's view that the study is technically possible and that you agree with it.

B. Adaptation according to Annex XI, Section 3

Annex XI, Section 3 states that testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report (CSR), by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I, and by communicating the specific conditions of use through the supply chain. In particular:

- 3.2 (a): "*the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled,*
  - *i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;*
  - ii. *a DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;*"

You justified your adaptation with the following: "*The discharged concentrations of the substance into the surface water are likely to be low.*"

Your reported environmental exposure estimates in the CSR, obtained with EUSES modelling. Since the substance is poorly water-soluble, a PNEC based on a long-term study, i.e. data from an OECD 211 study, would be required in addition to the exposure estimates. Therefore, the submitted data is not sufficient for adaptation and your adaptation under Annex XI, Section 3 is rejected.

As detailed above, the request in the original decision was not met, and you are still required to provide information on Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20/OECD 211) with the Substance.

Appendix 2: Procedural history

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision TPE-D-2114346840-50-01/F. The Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 40 of the REACH Regulation.

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft of this decision was notified to the Member States Competent Authorities according to Article 51(1) of the REACH Regulation.

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 comment and did not amend the request(s).

The comment referring to cease of manufacture which does not relate to the content of this decision, has been addressed in a separate communication to you.

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: Further information, observations and technical guidance

1. This decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. The Article 42(2) notification for the original decision is on hold until all information requested in the original decision has been received.