Helsinki, 8 November 2019

Addressee: [redacted]

Decision number: CCH-D-2114489545-34-01/F
Substance name: Benzoic acid, C12-15-alkyl esters (the Substance)
EC number: 270-112-4
CAS number: 68411-27-8
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 6 December 2018

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

By decision CCH-D-2114375450-52-01/F of 9 November 2017 ("the original decision") ECHA requested you to submit information by 19 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:

Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats

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.[1] 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[2].

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.

Authorised[3] by Wim De Coen, Head of Unit, Hazard Assessment

[1] Only the final decision will be sent to the National enforcement authority so they can consider enforcement actions.
[2] 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
[3] 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

This decision is necessary according to Article 42(1) of the REACH Regulation because in your updated registration as a response to the decision CCH-D-2114375450-52-01/F ("the compliance check decision") you have provided information that ECHA has assessed for compliance with the information requirements of the REACH Regulation and the outcome is that your registration still does not comply with the information requirements addressed in the compliance check decision.

0. Assessment of the read-across approach

Legal framework

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[4] and related documents[5, 6].

Information provided

In the compliance check decision you were requested to submit information derived with the registered substance [redacted] (the Substance). In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on (bio) transformation to common compound(s) and have provided experimental studies with the Substance and source substance Benzoic acid isononylester [redacted] (EC 447-010-5, key study) and have provided read-across justification documentation.

Evaluation of the adaptation

ECHA has assessed your adaptation in the light of the requirements of Annex XI, Section 1.5 of the REACH Regulation and considers that the read-across cannot be accepted for the reasons presented below.

Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*adequate and reliable documentation of the applied method shall be provided*". Within this documentation "*it is important to provide supporting information to strengthen the rationale for the read-across*"[7]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9
[5] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[6] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394
[7] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

from the data on the source substance(s).

The documentation of your adaptation must include information to assess the impact of exposure to non-common compounds and to confirm your claimed worst-case prediction.

As indicated above, your read-across hypothesis is based on the (bio)transformation of your Substance and source substances to a common compound. In this context, it is important to consider the rate and extent of the formation of the common compound and to determine whether exposure to constituents of the Substance and source substance in their esterified forms may occur. The impact of such exposure on the prediction of properties of the Substance needs to be assessed to ensure that a reliable prediction can be made.

You have provided experimental data on the hydrolysis behaviour of the Substance and of the source substance indicating similar rates and extent of hydrolysis of the constituents of these substances. This data reveals that a significant proportion of the constituents of both substances remains non-hydrolysed after 4 hours of exposure. Therefore, exposure to constituents of the Substance and source substance in their esterified forms may occur. You have considered that the length of the alkyl chain length is the only difference affecting the systemic uptake of the Substance and source substance after oral administration. You have explained that the source substance has a shorter alkyl chain than the Substance and therefore can be considered as a "*reasonable worst-case*" surrogate for read-across purposes. You have concluded that "*any parent ester that is not hydrolysed to benzoic acid and the corresponding fatty alcohol would not present an additional toxicological hazard*". You have not provided information to support your claims on the comparative absorption potential and toxicological hazards of the constituents of the Substance and source substance in their esterified form.

Relevant, reliable and adequate information allowing to compare the properties of the Substance and source substance is necessary to assess the impact of exposure to the constituents of the Substance and source substance in their esterified form. Information on systemic bioavailability and toxicological properties can be obtained, for example, from bridging studies of comparable design and duration for the Substance and the source substances. In the absence of such information i.e. bridging studies, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance.

Conclusion

For the reasons presented above and on the basis of the information provided in your registration dossier, ECHA considers that there is not sufficient support for your proposal that the Substance and the source substance have similar toxicological properties as result in structural similarity, common breakdown products, and similarity in physico-chemical properties. For these reasons, ECHA considers that your hypothesis is not a reliable basis whereby the properties of the Substance may be predicted from data from the source substance.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

In the compliance check decision you were requested to submit information derived with the Substance for Sub-chronic toxicity study (90-day), via oral route.

In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on analogue approach and provided experimental studies according to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) with source

substance Benzoic acid isononylester [redacted] EC 447-010-5), and read-across documentation.

ECHA considers that the read-across cannot be accepted for the reasons outlined above.

In you comments to the draft decision, you still consider the applied read-across approach to be valid, however you have not provided any new supporting information to support the read-across approach. In addition, you acknowledged that performing a so called "bridging study" could confirm the read-across approach applied by you.

As detailed above, the request in the original decision was not met, and you are still required to provide information on Sub-chronic toxicity study (90-day), via oral route (Annex IX, Section 8.6.2); test method: EU B.26/OECD TG 408 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 CCH-D-2114375450-52-01/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 41 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 within 30 days of the notification.

ECHA took into account your comments and did not amend the request.

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.