ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 25 April 2018

Addressee: [redacted]

Decision number: CCH-D-2114407980-50-01/F
Substance name: Benzyl acetate
EC number: 205-399-7
CAS number: 140-11-4, 140-11-4, 140-11-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 07/11/2017
Registered tonnage band: Over 1000 tpa

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:[1]

1. **Spectral data (Annex VI, Section 2.3.5.);**
   - **Ultra-violet spectrum**
   - **Infra-red spectrum**
   - **Nuclear magnetic resonance or mass spectrum**

You may adapt the testing requested above according to the specific rules outlined in Annex VI 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 adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **1 August 2018**. You also have to update the chemical safety report, where relevant.

The reasons of 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.

[1] No testing for endpoints listed in Annexes IX or X to the REACH Regulation may be started or performed at this moment: A decision only becomes legally effective and binding for you after it has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

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[2] by Kevin Pollard, Head of Unit, Evaluation E1

[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. Spectral data (Annex VI, Section 2.3.5.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

Spectral data is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The registration dossier does not contain any spectral data.

ECHA regards the list of spectral data requirements (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) specified in the REACH Regulation as relevant to identify the registered substance.

In your attachment to your comments on the draft decision, you stated the following: "*Spectral data ECHA has requested the provision of spectral data: this is being generated and will be provided*".

ECHA understands that you agreed with the information requirement in the draft decision. In addition, you indicated your intention to address the information requirement in an update of the registration.

You provided an updated registration dossier (submission number: [redacted]). However, no new spectra data was included. All the new information in the later update(s) of the registration dossier will be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Accordingly, the Registrant should provide the missing spectral data; a ultra-violet spectrum, an infra-red spectrum and a nuclear magnetic resonance spectrum (a mass spectrum can be provided instead of a nuclear magnetic resonance spectrum) If it is not technically feasible or scientifically necessary to provide any of the spectral data listed then a justification must be provided in each case.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

Deadline to submit the requested information

In the draft decision communicated to you the deadline indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision requested spectral data (Annex VI, Section 2.3.5.), a Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species and Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats. As the Pre-natal developmental toxicity study and Extended one-generation reproductive toxicity study are not addressed in the present decision, ECHA considers that a reasonable deadline for providing the remaining information, spectral data in the form of an updated registration is 3 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

Appendix 2: Procedural history

You were notified that the draft decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation. However, following your comments on the draft decision and the inter-related further and substantial information provided in the updated dossier, for this specific case, ECHA has taken into account all the updated information, relevant, to the draft decision.

The compliance check was initiated on 08/06/2017.

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 requests and the deadline and modified Appendix 1.

ECHA took into account your comments and all the updated information of submission [redacted]. As a result, the requests for information on Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species and Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats were removed. For the remaining request for information on spectral data, Appendix 1 was modified.

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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present 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 your Member State.

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.