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Helsinki, 22 September 2016

Addressee: [redacted]

Decision number: CCH-D-2114344290-59-01/F
Substance name: oxydiethylene dibenzoate
EC number: 204-407-6
CAS number: 120-55-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 4 March 2016
Registered tonnage band: over 1000 tonnes/year

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. **Composition of each substance (Annex VI, Section 2.3.) of the registered substance**
   - **Concentration values;**
2. **Spectral data (Annex VI, Section 2.3.5) of the registered substance**
   - **Ultra-violet spectrum**
   - **Nuclear magnetic resonance or mass spectrum;**
3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2; test method: EU B.31/OECD TG 414) in rabbits, oral route with 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 of the REACH Regulation. In order 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 are required to submit the requested information in an updated registration dossier by **29 September 2017**. You shall also 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. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 and Annex X, Section 8.7 of the REACH Regulation.

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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/web/guest/regulations/appeals.]

Authorised[1] by Ofelia BERCARU, Head of Unit, Evaluation E3

[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.

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Appendix 1: Reasons

1. Composition of the substance (Annex VI, Section 2.3.)

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

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, the Registrant shall note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and 80% for multi-constituent substance) shall be identified and reported individually; and

- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.

- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier, you identified the registered substance as the well-defined mono-constituent substance *oxydiethylene dibenzoate* and specified the typical concentration level of > [redacted]% (w/w) for the main constituent *oxydiethane-2,1-diyl dibenzoate* (EC number 204-407-6 and CAS number 120-55-8) and the typical concentration level of <[redacted]% for the impurity [redacted] (EC number [redacted] and CAS number [redacted]). However, you did not report the concentration ranges for the main constituent and any impurity in the composition.

ECHA notes that up to [redacted]% of the composition has therefore not been accounted for. However, the analytical data attached in the dossier would indicate the presence of impurities required to be reported in the dossier.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

You are accordingly requested to correct the information provided on the composition of the registered substance and especially the part of the composition that is not reported, including other impurities.

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Regarding how to report the composition of the registered substance in IUCLID, the following applies: You shall report individually any constituent required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

You shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI.2.3.7. of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

2. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.)

Spectral data are a formal information requirement of Annex VI Section 2.3.5 of the REACH Regulation to establish and confirm the identity of the substance.

The ultra-violet (UV) and nuclear magnetic resonance (NMR) or mass spectometry (MS) data is not available in the registration dossier.

ECHA regards this required information scientifically relevant for the registered substance for the following reasons:

- The substance absorbs in the UV range due to the presence of chromophores in the constituents. A UV spectrum representing the absorption of these constituents in the UV range can therefore be recorded;

- NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling.

You are therefore requested to submit a UV spectrum, and an NMR spectrum, such as a ^{1}H-NMR or a ^{13}C-NMR. As an alternative to an NMR spectrum, mass spectra (MS) generated as part of mass spectroscopic analysis for the elucidation of the structure of the constituents in the substance can be provided.

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

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3. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route, according to OECD test guideline 414, using the registered substance as test material. In addition to this study, you also provided a supporting study on the embryo-fetal toxicity in rats by the oral route, following the principles of OECD TG 414, with the registered substance.

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

The technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by using a rodent species (rats). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbits as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

In your comments you agreed with the information requirement in the draft decision. Moreover, you make a request to perform "*preliminary work prior the selection of the exposure route (gavage vs diet)*" because of the possible "*incompatibility of the test material with gavage or oral administration routes*". ECHA notes that, according to Article 10, it is a requirement to submit proposals for testing where listed in Annexes IX and X. Studies which are not testing listed in Annexes IX and X may be performed without the need for a testing proposal.

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Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit) by the oral route.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 18 months. You sought to justify this request by informing ECHA that there is an *"increasing pressure on space within contract research organizations"* and that *"the reporting cannot be guaranteed"* in 12 months. However, you failed to substantiate your claims with any documentation from the CRO supporting this claim. Consequently, ECHA has not modified the deadline of the decision.

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Appendix 2: Procedural history

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 decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 6 April 2016.

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 did not amend the request(s) and the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

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

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfill the information requirement for the range of substance composition 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 substance tested in the new test(s) 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 test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.