ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114321379-48-01/F Helsinki, 14 March 2016

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For oxydipropyl dibenzoate, EC No 248-258-5 (CAS No 27138-31-4), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for oxydipropyl dibenzoate, EC No 248-258-5 (CAS No 27138-31-4), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission [redacted], for the tonnage band of 1000 tonnes or more per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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

The compliance check was initiated on 30 July 2015.

On 19 August 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the recept of the draft decision.

On 4 September 2015 ECHA received comments from the Registrant on the draft decision.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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

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

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

Name or other identifier of the substance (Annex VI Section 2.1.)

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **21 September 2016** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Information in the technical dossier related to the identity of the substance

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.

Name or other identifier of the substance (Annex VI Section 2.1.)

Annex VI, section 2.1 of the REACH Regulation requires that the registration dossier contains adequate and sufficient information to enable each substance to be identified.

ECHA notes that the Registrant identified the registered substance as a well-defined multi-constituent substance. According to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, well-defined substances are these with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical speciation, including structural information. This implies that constituents of well-defined substances must have a clearly defined chemical identity and a unique definitive molecular formula. A multi-constituent substance consists of several main constituents which are present at concentrations generally ≥ 10% and < 80% (w/w) and they are named as a reaction mass of two or more main constituents.

In the present dossier the substance has been identified as a multi-constituent substance and identified by a generic EC entry (248-258-5) and CAS number (27138-31-4) that refer to "Dipropylene glycol dibenzoate". In "Dipropylene glycol dibenzoate" the position of the methyl group of the propylene glycol moiety is not defined and therefore the abovementioned EC and CAS entries cover a substance containing all possible structural isomers 1-{[1-(benzoyloxy)propan-2-yl]oxy}propan-2-yl benzoate, oxydipropane-1,2-diyl dibenzoate and oxydipropane-2,1-diyl dibenzoate) as main constituents.

However, the IUPAC name specified in section 1.1 ([redacted]) refers to only one of these constituents and therefore describes only a mono-constituent substance and does not cover all constituents of "Dipropylene glycol dibenzoate". Therefore it is inconsistent with EC and CAS identifiers. Furthermore the structural formula given refers to only one of the impurities listed [redacted] and therefore is not representative for the composition and is also inconsistent with the EC and CAS identifiers and IUPAC name given.

In section 1.2 of the technical IULCID dossier the Registrant has listed four constituents:

[redacted]

as the main constituents, only 2 of them being isomers of "[redacted]". Among the four impurities listed ([redacted] and [redacted]) only [redacted] can be regarded as an isomer of "[redacted]". Therefore, the EC and CAS entries for "Dipropylene glycol dibenzoate" cover only some of the main constituents specified in section 1.2, but not all of them. Up to [redacted]% of the constituents listed in section 1.2 [redacted] are not covered by the "Dipropylene glycol dibenzoate". In addition, "Dipropylene glycol dibenzoate" covers constituents that are not present in section 1.2 neither as main constituents nor impurities.

ECHA therefore concludes that the substance has not been sufficiently identified and the identifiers currently used are inconsistent and not representative for the registered substance.

Based on the information given, the substance could be more appropriately identified as a Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) instead as a multi-constituent substance, because of the relatively large number of constituents and the variability of the composition.

Accordingly, the Registrant is requested to clarify the identity of the substance and ensure that the information is consistent throughout the dossier.

In case when the Registrant decides to identify the registered substance as a multi-constituent substance, the main constituents present at concentrations generally ≥ 10% and < 80% (w/w) need to be taken into account when naming the substance and the generic format used for naming multi-constituent substances is "Reaction mass of [IUPAC names of the main constituents]".
In case when the Registrant decides to identify the registered substance as a UVCB substance, the following applies:

a) The naming of the UVCB substances consists of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014). The chemical name shall cover ≥ 80% (w/w) or, if such group does not exist, all the groups present at a concentration of ≥10% (w/w).

b) The description of the manufacturing process shall cover the starting material used, ratio of the starting materials, steps and relevant process parameters. ECHA notes that the Registrant has indicated in section 3.1 one of the starting materials as "one or more glycols", which may suggest that different starting materials are used. It needs to be taken into account that according to the Guidance any significant change of source or process would be likely to lead to a different substance that should be registered again. As a result the different glycols used in the process may result in different substances.

Regardless of the substance type chosen all identifiers (EC and CAS numbers and names, IUPAC name and structural and molecular information) given in section 1.1 need to be consistent with each other.

As for the reporting of the information in IUCLID, the following applies:

The registrant shall decide first whether the substance is to be identified as a multi-constituent substance or a UVCB substance.

In case of a multi-constituent substance the substance is named as a "Reaction mass of [IUPAC names of the main constituents]" and this name is indicated in the IUPAC name field in IUCLID section 1.1. The main constituents shall be consistent with the constituents listed in IUCLID section 1.2 as "constituents".

In case of a UVCB substance the chemical name and the manufacturing process description shall be specified in the "IUPAC name" and "Description" field in IUCLID section 1.1, respectively. All constituents are to be listed under "constituents" as the terms "main constituents" and "impurities" are not regarded as relevant for UVCB substances.

Further technical details on how to include the name and report the composition of a multi-constituents substance or UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2 of 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.

As the EC identifier currently assigned to the registered substance does not fully correspond to the registered substance, the Registrant shall not at this stage remove or modify this EC entry for technical reasons, as the registration is linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however specify in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 248-258-5 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Regarding the CAS entry, the appropriate CAS entry shall be included in the "CAS information" field, if available. Where the current CAS entry (CAS number 27138-31-4) does not identify the registered substance, it should be reported under the "Related CAS information" field in IUCLID section 1.1.

The Registrant should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Under this compliance check, the process of adapting the identifier can however only be applied once ECHA is in a position to establish the identity of the substance intended to be covered by the Registrant with this registration. Should the information submitted by the Registrant as a result of this decision indicate that the process of adapting the identifier is relevant, ECHA

will inform the Registrant in due time as to when this process shall be initiated. The Registrant should note that the application of the process of adapting the identifier is without prejudice to the requirements specified in this decision.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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.