Decision number: CCH-D-2114321113-70-01/F Helsinki, 22 March 2016

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

For 2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate**, EC No** 243-885-0 **(CAS No** 20566-35-2**), 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 2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate, EC No 243-885-0 (CAS No 20566-35-2), submitted by [redacted] (Registrant).
The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [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.

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 16 April 2015.

On 25 August 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 1 October 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. As a result, the information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 21 January 2016 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:

1) Name or other identifiers of the substance (Annex VI Section 2.1.1 of the REACH Regulation)

2) Composition of each substance (Annex VI Section 2.3 of the REACH Regulation)

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 **29 June 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.

A. 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.

1) Name or other identifiers of the substance (Annex VI Section 2.1.1 of the REACH Regulation)

Appropriate identifiers for the registered substance shall be provided as required according to Annex VI Section 2.1 of the REACH Regulation.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist 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) - referred to as "the Guidance" thereinafter.

(1) Chemical name inconsistent with substance type

The chemical name and the EC 243-885-0 and CAS 20566-35-2 identifiers reported in IUCLID section 1.1 refer to 2-*(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate*. This name corresponds to a substance which composition includes the two stereoisomers of *2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate* as main constituents (i.e. each present in the substance at concentration levels between 10% and 80%). Therefore, the chemical name and the EC and CAS identifiers correspond to a multi-constituent substance.

Additionally ECHA notes that:

- The Registrant included the following description for the substance composition in section 1.2 of the IUCLID dossier:

  "[redacted] with [redacted] leading to the formation of a complex mixture of products with different combinations of these three reagents."

- The composition and chromatographic data provided in the registration dossier report several groups of constituents covering different combinations of [redacted]

- [redacted] is not reported as such in the composition information and is reported as part of one of the above-mentioned groups of constituents, that has been described as

  "Unspecified. Including [redacted] as well as other components with 1 unit of [redacted]."

The above mentioned information reported in the IUCLID dossier confirms the UVCB nature of the substance.

Therefore, name and EC and CAS identifiers provided in section 1.1 of the IUCLID dossier are not consistent with the reported type of substance (UVCB) and are not consistent with the composition and analytical data reported for the registered substance.

Consequently, the information reported in section 1.1 of the IUCLID dossier is not consistent through the dossier. Consequently the identity of the substance cannot be verified.

The Registrant is accordingly requested to revise the identifiers of the substance to ensure that consistent information regarding the identification of the substance is reported in the dossier.

The IUPAC name shall be representative of the specific substance which is the subject of this registration and shall be derived according to the naming conventions specified in Chapter 4 of the Guidance.

The Registrant is furthermore requested to ensure that the CAS information assigned to the substance specifically corresponds to the registered substance.

If the EC entry is not corresponding to the registered substance, the Registrant shall however not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 243-885-0 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.

(2) Description of the manufacturing process must be reported

ECHA notes that the description of the manufacturing process is missing from the dossier.

The Registrant is accordingly requested to provide the description of the manufacturing process with information that clearly defines the identity of the substance. The information submitted must include the following:

- Identification and molar ratio of the starting materials,
- Description of the relevant steps,
- Process parameters that affect the composition of the substance, (e.g. the parameters used to control the degree of polymerisation), and
- Isolation/purification steps.

As for reporting the above requested information in IUCLID:

- The chemical name shall be reported in the "IUPAC name" field of the reference substance in IUCLID section 1.1.
- Any available and appropriate CAS entry for the registered substance shall be reported under the "CAS information" header of the reference substance in IUCLID section 1.1. Should the reported CAS number not be specific but related to the registered substance, it may be reported under the "Related CAS information" header in IUCLID section 1.1.
- The manufacturing process description shall be reported in the description field in IUCLID section 1.1.

Further technical details on how to report the identifiers of UVCB and well-defined substances in IUCLID are available in paragraph 2.1 of the Data Submission Manual 18 on the ECHA website.

The Registrant outlined in the comments to the draft decision that the request to provide a more detailed description of the manufacturing process should be revised because it is not a specific request in Annex VI, section 2.1 and because the description of the manufacturing process for an imported substance is not mandatory in terms of the REACH Regulation.

ECHA points out that Annex VI, section 2 provides that "*...the information given...shall be sufficient to enable each substance to be identified.*" As indicated in chapter 4.3 of the Guidance, UVCB substances are substances that cannot be sufficiently identified by their composition, because:

-the number of constituents is relatively large and/or

-the composition is, to a significant part, unknown and/or

-the variability of the composition is relatively large or poorly predictable.

As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition. For UVCB sub-type 2 substances, where the source is chemical or mineral and the process is a synthesis, such as is the case with the registered substance, chapter 4.3.1.2 of the Guidance specifies: "*The identification of a reaction product is based on the starting materials for the reaction and on the (bio)chemical reaction process in which the substance is generated. ...A main identifier for reaction products is the description of the manufacturing process. For substance identification, the final or most relevant process step shall be given. The chemical process description shall be a generic description of the type of process (e.g....) together with relevant process circumstances.*" As explained in the Guidance: "*The consequence of defining a substance as a UVCB is that any significant change of source or process would be likely to lead to a different substance that should be registered again*".

Therefore information on how a UVCB substance is manufactured is essential for establishing identity. ECHA highlights that the need of establishing the identity of a substance is independent on whether the substance is manufactured or imported.

Additionally, the Registrant also mentioned in his comments that the identifiers name and CAS entry of the substance will be revised to better describe the substance.

2) Composition of each substance (Annex VI Section 2.3 of the REACH Regulation)

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

In that respect, according to chapter 4.3 of the Guidance, the Registrant shall note that for UVCB substances presenting a large number of constituents, such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually,

- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature.

For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In order to provide the clearest possible description of the composition of the manufactured substance, the reported groups of constituents shall be described as precisely as possible.

ECHA notes the following:

- In the present dossier the Registrant reported six groups of constituents and the corresponding typical concentrations, however the concentration ranges of those groups of constituents were not provided.
- One of the group of constituents ("[redacted]") is generically described as [redacted] ECHA notes however that the chromatographic data ([redacted]) reported in section 1.4 of the IUCLID dossier indicates that a further breakdown of this group of constituents based on the number of [redacted] is possible. This information would provide a clearer characterization of the composition of the substance.
- The CAS [redacted] and name "[redacted]" (CAS) provided for first reported group of constituents describes a UVCB substance consisting of all possible combinations of the reaction between [redacted].

  On the other hand the Registrant describes this group of constituents as a limited subset of the possible combinations of the reaction between these reactants.

  Therefore, the CAS [redacted] and corresponding name provided for this group of constituents is not consistent with the description given.

Without the concentration ranges of the different group of constituents and a complete and consistent description of the constituents of the substance is not possible to verify the actual composition of the substance and therefore its identity.

Therefore, the information provided is not sufficient to verify the composition of the registered substance.

The Registrant is accordingly requested to provide the concentration ranges for all the reported groups of constituents and more detailed information on the group of constituents "[redacted]". The Registrant shall note that, for substances such as the registered substance, reporting unknown constituents according to the identity and number of units which these constituents consist of is normally required.

Regarding how to report the composition in IUCLID, the following applies:

- The Registrant shall indicate the composition of the registered substance in IUCLID Section 1.2.
- For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.
- For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 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. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

The Registrant shall ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the quantification of the constituents required to be reported, as required under Annex VI, section 2.3.7.

The Registrant outlined in the comments to the draft decision that a further identification of the constituents, revising the description of the types of constituents and providing the information available on the main constituents (> 10% w/w), will be provided.

ECHA notes that this information could be valuable for the identification of the substance. However, based on the information already reported in the IUCLID dossier, a more detailed information on the specific group of constituents ("[redacted]") based on information available in IUCLID section 1.4 would be sufficient to fulfil the request regarding the missing information on the identification of the constituents of the substance. ECHA clarifies that it is not requesting the Registrant to perform new analyses but instead to use the detailed results of the reported analysis in IUCLID section 1.4 to provide more information regarding the above mentioned group of constituents, i.e. subdividing the groups of constituents based on the number of [redacted]

Additionally, the Registrant mentioned in his comments that it might not be possible to derive the typical, minimum and maximum levels of the constituents as sophisticated chemical analysis that are not part of the routine analysis are necessary.

ECHA understands that the analytical methods to derive the typical, minimum and maximum level of the constituents might not be routine analysis. However, this type of information can be extracted from analytical methods that are already reported by the Registrant and that ECHA considers being standard analytical methods.

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 Guilhem de Seze , Head of Unit, Evaluation E1

[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.