EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308088-52-01/F Helsinki, 8 September 2015

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

For Tetrabromobisphenol-A Glycidylether (TBBA-GE), EC No 500-107-7 (CAS No 40039-93-8), 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 Tetrabromobisphenol-A Glycidylether (TBBA-GE), EC No 500-107-78 (CAS No 40039-93-8), 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. ECHA stresses that it has not checked the information provided by the other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted] 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.

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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 September 2014.

On 17 April 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. By 25 May 2015, the Registrant did not provide any comments on the draft decision to ECHA.

On 23 July 2015, ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant 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:

a. Name or other identifier of the substance (Annex VI, 2.1.);
b. Composition of the substance (Annex VI, 2.3.);

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of 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.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, in that case it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

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 **15 December 2015** 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.

(a) Name or other identifier of the substance (Annex VI, 2.1. of the REACH Regulation.)

Article 5 of the REACH Regulation sets the obligation to register substances manufactured or placed on the market within the Community. In accordance with Annex VI, Section 2 the information provided on the name and other identifiers shall enable the registered substance to be unambiguously identified.

ECHA notes that the Registrant provided information on the identity of the registered substance that consists of a set of data including name, identifiers, type of substance and explanatory statements on the substance identity that are incompatible with each other.

- ECHA notes that the Registrant specified for the registered substance the identifier EC 500-107-7 and chemical name corresponding to the substance "2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane".
  These identifiers refer to a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) which composition includes a multitude of constituents including isomers obtained from the reaction of 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol with 1-chloro-2,3-epoxypropane.

- The chemical name and EC identifier specified for the registered substance refer to a No Longer Polymer (NLP) under the 7th amendment of Directive 67/548/EEC.

  The Registrant shall note that the NLP list (version 3, available on EU Bookshop website managed by the Publications Office of the European Union in Luxembourg at https://bookshop.europa.eu) specifies the following: "*Mixture of oligomers or isomer mixtures are generally listed in the no-longer polymer list with the name of the main component only when present in the mixture with 80% or more*".

  The name provided "**2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane**" corresponding to EC entry 500-107-7 refers to "oligomeric reaction products". No specific "main component" is described in the name, the "main component" designating in this case constituents or a group of constituents presenting the same level of oligomerisation (e.g. monomers, dimers, trimers).

  As a consequence, the substance described by this EC number and name does not include any constituent or group of constituents (such as monomers, dimers, trimers...) at concentration levels of 80% or more.

- The Registrant identified the registered substance as a mono-constituent substance. According to the Guidance, a mono-constituent substance is a substance in which one main constituent is present to at least 80%. A mono-constituent substance is named after the main constituent.
  Considering that the name assigned to the registered substance refers to a UVCB substance that does not include any constituent at concentration levels of 80% or more, ECHA concludes that the identification of the substance as mono-constituent substance is inconsistent with the chemical name provided.

- The Registrant reported the following text in the remarks field in IUCLID section 1.1 "*Brominated Epoxy having Epoxy Equivalent of* [redacted] *is an oligomeric mixture. Thus, the substance appearance is composition depended. A typical composition*

forms a light-yellow viscous waxy solid with unidentified particles. A substance composition containing [redacted] of the smallest component (n=0) is a solid with identified particles"
This statement would indicate that the registration covers at least a composition consisting of [redacted] of a group of constituents (n=0) with a specific oligomerisation level, i.e. 2,2'-{propane-2,2-diylbis[(2,6-dibromo-4,1-phenylene)oxymethylene]}dioxirane. As explained hereinabove, the chemical name and the NLP entry with EC number 500-107-7 are not appropriate for the identification of a substance comprising a 'component' in a concentration exceeding 80%. A substance with this composition would in fact be regarded as a well-defined substance and more specifically to a multi-constituent substance consisting of the 3 possible stereoisomers as main constituents.

The information included in the remarks field in IUCLID section 1.1 is thus inconsistent with the name, EC identifier and type of substance reported.

ECHA therefore concludes that the information currently included in the registration dossier refers at the same time to a mono-constituent substance, to a multi-constituent substance and to a UVCB substance.

The Registrant is accordingly requested to clarify the identity of the registered substance, by ensuring that the information reported throughout the dossier consistently supports the actual composition of the substance. Taking into account the information given on the composition and analytical data, ECHA foresees two possibilities: (i) the registered substance refers to a UVCB substance, (ii) the registered substance refers to a well-defined multi-constituent substance.

(i) If the substance subject to this registration is the UVCB substance "2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane", the Registrant shall note that the naming of UVCB substances shall consist of two parts: the chemical name and the 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 2013), referred to thereinafter as "the Guidance". However, no description of the manufacturing process is currently available in the registration dossier.
Therefore the Registrant shall provide a detailed description of the manufacturing process, including:

- The identity and ratio of the starting materials.
- Description of the manufacturing steps in the order they occur.
- For each step, all relevant process parameters that affect the composition and therefore the identity of the substance must be provided.
- Regarding more specifically the steps involving a chemical transformation, the Registrant shall describe the oligomerisation, including the parameters used to initiate, propagate and terminate the oligomerisation reactions. The information shall be supplemented with details of the reaction mechanisms involved. Where the oligomerisation involves catalytic reactions, the information shall include, for each catalytic reaction, details of the type of catalyst(s) used in terms of reaction(s) that they catalyse (including detailed information on the selectivity of the catalyst towards the reaction products, reaction mechanisms etc.).The information on how the use of

the specific catalyst affects the composition of the registered substance must be also included. The present request is not limited to the catalytic reactions, but concerns all oligomerisation steps.

- Information on any processing step applied to isolate the manufactured substance.

Finally, the Registrant shall revise the following information:

- The Registrant shall delete the CAS number 40039-93-8 reported as CAS information for the registered substance for the reason explained hereinafter. The Registrant shall specify instead any CAS number specifically corresponding to the registered substance (if available).

  The CAS name for the entry with this CAS number is "Phenol, 4,4'-(1-methylethylidene)bis[2,6-dibromo-, polymer with 2-(chloromethyl)oxirane". This CAS number 40039-93-8 is linked in the No-Longer Polymer (NLP) list (version 3, available on EU Bookshop website managed by the Publications Office of the European Union in Luxembourg at https://bookshop.europa.eu) to the EC entry 500-107-7 also assigned by the Registrant to the registered substance.

  The Registrant shall note, however, that as explained in the NLP list (page 8 of the document) "NLP-Nos and name descriptions take precedence. The CAS-RN given are to be treated as indicative and for a use as a searching tool". ECHA considers that the CAS information included in the registration dossier is generic and therefore does not sufficiently describe the registered substance. Indeed the CAS name includes a reference to "polymer" whilst the NLP list is an inventory of substances which do not meet the definition of polymer within the meaning of Article 3(5) of the REACH Regulation.

- The Registrant shall change the substance type from mono-constituent substance to UVCB substance.

(ii) If the substance subject to this registration is a well-defined multi-constituent substance, the Registrant shall specify a chemical name according to the naming conventions specified in Chapter 4.2 of the Guidance.
The Registrant is furthermore requested to delete from the dossier the CAS information currently assigned to the substance and to provide instead any available CAS information specifically corresponding to the 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 500-107-7 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.

The Registrant is requested not to revise the selected substance type from mono-constituent substance to multi-constituent substance. For technical reasons the Registrant would not be able to modify this information through a dossier update.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different manufacturing processes.[1] In these cases, the Registrant shall provide the required information on the starting materials, manufacturing process and constituents of each grade separately.
ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration. In order to enable registrants to correct initial registration mistakes, ECHA has developed a process allowing registrants to adapt the actual scope of existing registration.
Concerning the EC identifier, the Registrant shall note that the EC entry with EC number 500-107-7 normally corresponds to a UVCB substance consisting of at least 80% of oligomers and where none of those oligomers with the same level of oligomerisation (e.g. 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, dimers with 1-chloro-2,3-epoxypropane; 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, trimers with 1-chloro-2,3-epoxypropane..) is typically present at a concentration of at least 80%. If such group of constituents occasionally exceeds 80%, The EC entry can still be used.

The Registrant shall also note that substances consisting of 80% or more of a group of constituents with the same level of oligomerisation are normally regarded as different substances than those where the concentration of such constituents never exceeds 80% and shall be registered separately.

As for the reporting of the information in IUCLID, the chemical name and manufacturing process description should be specified in the "IUPAC name" and "Description" field in IUCLID section 1.1, respectively. Any CAS number specifically corresponding to the registered substance (if available) should be specified under the "Related CAS information" header in IUCLID section 1.1.

The Registrant shall ensure that the name and other identifiers reported in section 1.1 of the IUCLID dossier are consistent with the compositional information on the substance which is the subject of this registration.

b) Composition of the substance (Annex VI, 2.3. of the REACH Regulation)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations. In accordance with Annex VI, Section 2 the information provided on the composition shall enable the registered substance to be unambiguously identified.

ECHA notes that the registration does not contain sufficient and complete information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

As explained hereinabove, the information provided in the registration dossier does not enable identifying if the registered substance is of UVCB nature or is a well-defined substance.

The Registrant shall note that according to the Guidance:

[1] A manufacturing process is considered different whenever different sources are used and/or different processing steps and/or processing parameters are applied

- For UVCB substances, the chemical composition shall be given as far as known and the following applies:
  - All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
  - All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
  - Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.

- For well-defined substances, the following applies:
  - Each main constituent 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 or group of constituents, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

ECHA notes the following in relation to the compositional information provided in the registration dossier:

In section 1.2 of the IUCLID dossier, the Registrant reported one generic group of constituents "2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane" corresponding to the generic name given to the registered substance.

- The minimum concentration level reported for such group of constituents is [redacted]% (w/w). Besides this group of constituents, one impurity is reported with maximum concentration level [redacted]% (w/w).
  This means that summing up these values, only [redacted]% of the composition is accounted for.
- The Registrant provided the following statement in the Remarks field of the corresponding group of constituents in IUCLID:

  "Component n=0. A substance composition containing [redacted]% of this component is a solid with identified particles. This component is been considered as worst case scenario, based on the following considerations: 1. Molecular size - the smallest component 2. Molecular weight - the smallest component 3. Water solubility - the most water soluble component. Thus, phes-chem values of this component are been taken for assessment and analytical methods were developed to detect concentrations of this component in various studies. Component n=1 typical concentration [redacted]% (range [redacted]%). Component n=2 typical concentration <[redacted]% (range [redacted]%)"

  From such statement ECHA understands that the substance may correspond to
  - A UVCB substance consisting of oligomers with variable repeating units and
  - A well-defined substance including 92% of isomers of 2,2'-{propane-2,2-diylbis[(2,6-dibromo-4,1-phenylene)oxymethylene]}dioxirane.

- In the above-mentioned statement, the Registrant makes reference to three groups of constituents: "components n=0, n=1 and n=2". For two of these "components n=1 and n=2" information on minimum, maximum, and typical concentration values is provided.

For the group of constituents described as "component n=0" no concentration range is provided. For such group a concentration value is specified, however, no information is given on whether this value corresponds to a typical concentration level.

Taking into account that a significant part of the composition of the registered substance is unaccounted for, that the information given on the composition refers both to a UVCB substance and to a well-defined multi-constituent substance and that information on the specific concentration values for one of the reported groups of constituents is missing, ECHA concludes that the reported composition is not appropriate and has not been provided to the required level of detail.

The Registrant is accordingly requested to provide the missing compositional information of the registered substance and to remove from the dossier any compositional information referring to a different substance than the specific substance covered by this registration. The Registrant shall specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported.

Well-defined substances
If the substance subject to this registration is a well-defined multi-constituent substance the Registrant shall amend the compositional information reporting the main constituents and any impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance.

UVCB substances
If the substance subject to this registration is a UVCB substance the Registrant shall amend the compositional information provided as explained hereinabove, in accordance with the conventions specified in Chapter 4.3 of the Guidance.
Concerning the reporting of the unknown constituents, the Registrant shall note that, unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. Regarding the reporting of the oligomeric constituents a distinction according to the degree of oligomerisation is required for this purpose as a baseline.

Where the Registrant covers different grades of the substance in a registration, the Registrant shall report separately the starting materials, manufacturing process and the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

More generally, the Registrant should note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations. ECHA has established processes, subject to certain conditions, enabling Registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

Regarding how to report the composition in IUCLID, the following applies, the technical details on how to report the composition of UVCB and well-defined 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: 1.0, June 2010) on the ECHA website. The Registrant shall follow these technical details.

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 description shall be sufficient for the methods to be reproduced and therefore include details of the experimental protocol followed, any calculation made and the results obtained.

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[2] by Ofelia BERCARU, Head of Unit, Evaluation

[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.