EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114328635-47-01/F Helsinki, 25 April 2016

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

For 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether, List No 926-564-6, 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',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether, List No 926-564-6, submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section2 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 substance subject to the present decision is listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

The compliance check was initiated on 27 November 2014.

On 25 November 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments by 18 January 2016.

ECHA received no comments from the Registrant on the draft decision.

On 03 March 2016 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.), as specified under section III.(a) below;
b. Composition (Annex VI, 2.3.), as specified under section III.(b) below;
c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as described under section III.(c) below.

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.

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 **01 August 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.

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of over 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

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

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. ECHA noted incompliances relating to the manufacturing process description and has important remarks relating to the chemical name.

<u>Description of the manufacturing process</u>

The manufacturing process description reported by the Registrant in section 1.1 of the IUCLID dossier specifies the following:

- The registered substance is manufactured according to a [redacted] No specification of the relative ratio of propylene oxide used for the manufacturing was indicated.
- The manufacturing involves, according to the Registrant, the use of "[redacted]". Depending on the solvent used, different outcomes are obtained. More specifically, it is indicated that "[redacted]".

ECHA however considers that the description is not sufficiently detailed for an unambiguous identification of the registered substance. In particular, ECHA notes the following:

- The identity of the specific solvent used has not been indicated. ECHA underlines that the manufacturing process description indicates that alternative solvent types ([redacted]) may be used for the manufacturing and that the choice of the solvent will influence the composition of the manufactured substance. In the absence of information on the composition of the registered substance, ECHA considers that, based on the information in the current dossier, the differences in the compositions of the substances manufactured from different solvents may be so significant that they cannot all be registered in the same registration. Where the use of the [redacted] systematically leads to different constituents than those obtained with the [redacted], the substances manufactured using these different solvents shall be regarded as different substances under REACH.
- The exact ratio of all the starting materials used (including at least 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, propylene oxide, n-butyl glycidyl ether) has not been specified. Should the substance covered with this registration also involve the use of a "[redacted]", the ratio of that solvent relative to the other starting materials should also be specified but has not been reported in the registration dossier;
- Specifications of the process parameters used to control the composition of the manufactured substance, including the parameters determining the degree of oligomerisation, have not been included;
- The Registrant did not describe the steps applied to isolate the substance, including any eventual purification step undertaken.

As these abovementioned missing elements of the manufacturing process are expected to determine the composition of the registered substance, and taking also into account the limited information on the composition of the registered substance in the current dossier, ECHA considers that they are necessary for the identification of the substance.

The Registrant is therefore requested to clarify the identity of the substance which is the subject of this registration by providing the abovementioned missing information on the manufacturing process. For a clear illustration of the manufacturing process, the Registrant shall provide a description of the relevant chemical reactions taking place to manufacture the substance, in the form of chemical reaction scheme(s).

ECHA recognises that the Registrant may cover different compositions of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the source, manufacturing process and constituents of each composition. ECHA underlines that the reporting of a generic process description covering the manufacturing of different compositions may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that compositions for which a description would not be provided may eventually not be considered as being covered by the registration. The Registrant shall also note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

The Registrant shall note that the registration is currently linked to chemical identifiers (including the list number 926-564-6) for the substance "*2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether*". Should the substance intended to be covered by this registration refer to a different substance, the Registrant can however not remove or modify at this stage identifiers such as the list number for technical reasons, the registration being linked to that number 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 list number 926-564-6 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 should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

However, pending the resolution of all the incompliances highlighted in the present decision, the adaptation of the identifier can only be effective once ECHA is at least in a position to establish unambiguously 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 the present decision enable ECHA to identify the substance unambiguously, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform the Registrant in due time as to when the identifier adaptation process shall be initiated.

In any case, the Registrant should note that the application of the process of adapting the identifier does not affect his obligation to fulfil the requirements specified in this decision.

As for the reporting of the information in IUCLID, the manufacturing process description shall be specified in the "Description" field in IUCLID section 1.1. The chemical reaction scheme(s) shall be attached in section 1.4 of the IUCLID dossier.

The Registrant shall ensure that the chemical name and other identifiers reported in section 1.1 of the IUCLID dossier are consistent with the substance as described by the manufacturing process and representative of its actual composition. In particular, if the substance covered by this registration is manufactured using a [redacted], the Registrant shall ensure that the chemical name and other identifiers assigned to the registered substance take into account the reactants actually involved in the chemical reactions.

> *Important note to the Registrant on the chemical name:*
>
> *Regarding the naming of the substance covered by this registration, ECHA highlights that substances such as the registered substance are of oligomeric nature, so are also the substances listed 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). The Registrant shall note that the NLP list 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 "main component" designates in this case constituents or a group of constituents presenting the same level of oligomerisation (e.g. monomers, dimers, trimers).

ECHA notes that the result of the chromatographic analysis included in section 1.4 of the IUCLID dossier shows the presence of a peak having area % ca [redacted] which has been correlated to a molecular weight value corresponding to [redacted] g/mol. These data indicate that the composition of the registered substance may include a group of constituents at concentration levels close to the [redacted]% threshold value set for defining the above –mentioned rule of thumb for naming this type of substances.

Therefore, ECHA would like to highlight that the chemical name currently assigned to the registered substance "2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether" refers to "oligomeric reaction products". No specific "main component" is described in the name currently provided in the dossier. Based on this name, it is not possible to consider that the substance includes any constituent or group of constituents (such as monomers, dimers, trimers…) at concentration levels of 80% or more.

However, if the registered substance would exceptionally have a concentration level of any constituents or group of constituents of more than 80%, the current name would be considered appropriate.

In contrast, if the registered substance would have a typical concentration level of any constituents or group of constituents of more than 80%, the name currently provided would not be considered appropriate.

ECHA notes that the Registrant might have intended to cover under his registration compositions where concentration level of any constituents or group of constituents exceed exceptionally 80% and compositions where concentration level of any constituents or group of constituents typically exceed 80%. However in such case, the dossier would cover substances that shall normally be registered separately.

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

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.

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 for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, the Registrant should note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) 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 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 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.

ECHA notes that the Registrant did not provide any information on the identity and concentration levels of the constituents or groups of constituents present in the composition of the registered substance. The Registrant instead reported the composition as consisting of [redacted]% of the substance itself, i.e. of the "[redacted]".

ECHA therefore concludes that the reported composition has not been provided to the required level of detail.

The Registrant is accordingly requested to specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported. The Registrant shall note that, for substances such as the registered substance, reporting unknown constituents according to the identity, sequence and number of units which these constituents consist of and to the type of termination is normally required for this purpose as a baseline.

Where the Registrant covers different compositions of the substance in a registration based on different constituents, the Registrant shall report separately the source, manufacturing process and information on each composition covered. ECHA underlines that not reporting separately each composition may prevent ECHA from verifying that each composition corresponds to the substance covered by this registration. In addition, ECHA highlights that those individual compositions that are not reported in the IUCLID dossier may eventually not be considered covered by the registration.

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, should 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, should 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: 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 Registrant shall also ensure that the composition reported in section 1.2 of the IUCLID dossier is consistent with the substance as identified by its chemical name and other identifiers, including the manufacturing process. If the substance covered by this registration is manufactured using a reactive solvent, the Registrant shall ensure that the contribution of the reactive solvent to the structure of the constituents is taken into account in the composition to be reported.

(c) Description of the analytical methods (Annex VI, section 2.3.7.)

The description of analytical methods or the appropriate bibliographical reference for the identification of the substance is a formal requirement of Annex VI section 2.3.7.

The Registrant attached in the dossier the required set of spectroscopic fingerprints (ultra-violet, infra-red and proton nuclear magnetic resonance). These fingerprints can be used to support the presence of specific functional groups in the registered substance. The Registrant also reported a description of methods for the elemental analysis of the substance. The results from this analysis allow the determination of the carbon, hydrogen, nitrogen, oxygen and bromine elemental content of the analysed sample. The Registrant further submitted a gel permeation chromatographic analysis (GPC) which shows the existence of at least 6 constituents or groups of constituents.

However, it is not possible to derive from the described analyses the identity and concentration level of the constituents and groups of constituents required to be reported. Concerning more specifically the GPC chromatogram, the analytical report provided includes a peak table showing a correlation between elution volumes and molecular weight values. No further explanation is given clarifying how the different groups of constituents (e.g. oligomeric constituents bearing the same sequence and number of units) present in the registered substance have been identified and quantified. ECHA therefore concludes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance.

The Registrant is therefore requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. 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.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical 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[1] by Claudio Carlon, Head of Unit, Evaluation, E2.

[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.