EUROPEAN CHEMICALS AGENCY

Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350472-55-01/F
Substance name: 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane
EC number: 500-033-5
CAS number: 25068-38-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 31.08.2015
Registered tonnage band: 1000+T

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. **Name(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.) of the registered substance;**
   - **Chemical naming and corresponding EC entry**

2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Nature of constituents and their concentration values**

You are required to submit the requested information in an updated registration dossier by **21 March 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 of the REACH Regulation.

Appeal

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/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

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(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.)**

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.

According to chapter 4.2.1 of the "Guidance for identification and naming of substances under REACH and CLP" (Version 1.4 - June 2016), referred to thereinafter as "the Guidance", a mono-constituent substance is a substance in which one main constituent is present to at least 80%. Furthermore, a mono-constituent substance is named after the main constituent.

In addition, according to chapter 4.2.2 of "the Guidance" a multi-constituent substance is a substance in which at least two main constituents are present with ≥10% and <80% respectively. Please note that for the naming of a multi-constituent substance only main constituents typically present ≥ 10% contribute to the name following the generic format: "Reaction mass of [names of the main constituents]".

Furthermore, according to Annex VI section 2.1 of the REACH Regulation on the naming of a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) 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".

ECHA notes that you have identified the registered substance as a mono-constituent substance. However, you specified for the registered substance the numerical identifier EC number 500-033-5, and the chemical name *"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 [redacted].

Furthermore you stated in the document *"Summary - Composition of EC 500-033-5"* attached in section 1.4 of the IUCLID dossier that *"Although the substance that is made and sold in Europe for many years is registered as no-longer-polymer, the product that is typically sold in Europe [...] has >80% wt% of a single constituent. For this reason, we have described the substance as mono-constituent substance."* You also stated in the same document *"A certain percentage of products that are described using EC number 500-033-5 cannot be described as mono-constituent substance."*

Based on the above statements it is unclear to which substance this registration dossier refers to. Furthermore, ECHA concludes that the identification of the substance as mono-constituent substance is inconsistent with the chemical name provided, which refers to the name of a UVCB substance.Section 1.1 of the IUCLID dossier is lacking the description of the manufacturing process and the information provided in section 3.1 of the dossier is not sufficiently described. No information is provided on the ratio of the starting materials, the process parameters, and how the condensation process is controlled.

Furthermore, based on the broad concentration ranges, in particular on structure A, n=0 provided in the document "*Summary - Composition of EC 500-033-5*" it seems that more than one substance may be covered by this registration dossier.

You are 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 well-defined substance or (ii) the registered substance refers to a UVCB substance.

I. If the substance subject to this registration is a well-defined substance, you shall specify a chemical name according to the naming conventions specified in Chapter 4.2 of "the Guidance". You are 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 well-defined substance.

   In case the current identifiers are not appropriate to describe the registered substance, you should 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, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "*The EC number 500-033-5 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*". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance, e.g. 216-823-5. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

II. If the substance subject to this registration is the UVCB substance *4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane*, you 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 in "the Guidance". However, no detailed description of the manufacturing process is currently available in the registration dossier.

   Therefore you shall provide a detailed description of the manufacturing process, including:

   - The ratio of the starting materials.
   - 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, please 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 also be included.

In addition, you shall revise the following information:

- You shall delete the CAS number 25068-38-6 reported as CAS information for the registered substance for the reason explained hereinafter. Please specify instead any CAS number specifically corresponding to the registered substance (if available).
  The CAS name for the entry with CAS number 25068-38-6 is *"Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane"*. This CAS number 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 500-033-5 and also assigned by you to the registered substance.
  Please note the explanation in the NLP list (page 8 of the document) "NLP-Nos and name descriptions take precedence. The CAS-RN given is 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.

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

You 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.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration. Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision. Concerning the EC identifier, you shall note that the EC entry with EC number 500-033-5 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. [redacted].) 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.

You 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 thus 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 not specifically corresponding to the registered substance (if available) should be specified under the "Related CAS information" header in IUCLID section 1.1.
You 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.

In your comments to the draft decision you outlined your intention to address the information requirement, name and other identifiers of the substance (Annex VI, Section 2.1). Irrespectively of whether the newly provided information may be sufficient to meet the information requirement addressed in the decision, ECHA can already point out the following:

- You provided information outlining what the Epoxy Resins REACh Consortium (ERRC) decided.
- Furthermore, ECHA notes that you are referring to a 'boundary' composition (Final ERRG proposal 2016) on page 4 of the document "[redacted]". However, it should be noted that no information on your (as lead registrant) actual composition is included to identify and name the substance as a multi-constituent substance as proposed in the document "[redacted]".
- You should note that the ERRC's request to retain the CAS number 25068-38-6 for the multi-constituent substance with the name [redacted] is not possible, as CAS number 25068-38-6 does not refer to a well-defined substance. For the suggested multi-constituent substance ECHA would need to assign a new list number and link it to another CAS number, if available for this multi-constituent substance. However, you can include CAS number 25068-38-6 and corresponding CAS name under the "Related substances" information of the Reference substance.
- Furthermore, you should note that while "the Guidance", allows deviation from the rule for a multi-constituent substance as outlined in chapter 4.2.2.2, there is also a clear indication that for mono-constituent substance one main constituent is present to at least 80% and therefore the minimum concentration of 80% (w/w) of the main constituent is allowed.

- You should also note that the substance, considering the stereochemistry of the substance and the chemistry involved in the manufacturing process, ECHA understands that the two entries presented as the main constituents (referred to as "[redacted]" hereinafter) and those referred to as impurities, e.g. [redacted] do not describe individual constituents but instead groups of constituents (each stereo-isomer being a constituent in its own right). Therefore it is questionable that the substance for the suggested 'boundary' composition for resins with [redacted] fulfils the rules of multi-constituent substance as outlined in chapter 4.2.2 of "the Guidance". Therefore, each of the compositions is expected to have more constituents than actually listed in the document "[redacted]". Depending on the complexity of the composition (especially the number of isomers present), the compositions may still be considered as UVCB substance. As already pointed out in the draft decision, if the UVCB substance consists of at least 80% of oligomers and none of those oligomers with the same level of oligomerisation is typically present at a concentration of at least 80%, ECHA would consider the use of the EC entry with EC number 500-033-5 appropriate to identify the substance.
- ECHA acknowledges your comment that *"some registrants have realised that another, similar substance had been registered under this registration. These registrants have decided to submit a separate mono-constituent substance dossier for CAS [redacted] / EC [redacted]."* However, it is unclear if you (as lead registrant) are also submitting a registration dossier for the substance with CAS [redacted] / EC [redacted] (i.e. [redacted]).
- You should note that the structure of [redacted] contains chiral centers. As already explained above, [redacted] represents a group of constituents (stereo-isomers) and therefore it is questionable that the substance "[redacted]" for the suggested composition with [redacted]% [redacted]%, fulfils the rules of mono-constituent substance as outlined in chapter 4.2.1 of "the Guidance". Therefore, each of the compositions is expected to have more constituents than actually listed in the document "[redacted]" and depending on their number, compositions would be considered as well-defined substance.
- 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. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

2. Composition of the substance (Annex VI, Section 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.

In accordance with Annex VI, Section 2 the information provided on the composition shall enable the registered substance to be unambiguously identified. In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.4 – June 2016) – referred to as "the Guidance" thereinafter, the Registrant shall note that:

I. 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.

Furthermore, according to chapter 4.3 of "the Guidance" the Registrant shall note that:

II. 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 each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

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.

However, in section 1.2 of the IUCLID dossier, you reported the composition as one generic constituent "[redacted]" with typically [redacted]% and the concentration range [redacted]%.
You further included in the remarks field of the reference substance the following statement: "[redacted] *- see explanation given in section 1.4 of this REACH registration dossier."*
In addition, in section 1.4 of the dossier analytical data are provided for the compositions of [redacted].

Based on the results from the quantification by HPLC the compositions of [redacted] could be considered as being the same substance because the results show that structure A, n=0 (CAS number [redacted]) is present in all compostions from [redacted] [Area]% and all other constituents are present below [redacted] [Area]%, in particular structure A, n =2 is below [redacted] [Area]%. However, they do not correspond to the compostion as reported in section 1.2 of the dossier.

Considering the quantification results of [redacted], it seems that these compositions refer to the substance with EC number [redacted] and CAS number [redacted] and therefore it is unclear why EC number 500-033-5 was chosen in section 1.1 of the IUCLID dossier for idenfying your substance. Furthermore, it is unclear, why you decided to include CAS number [redacted] under related CAS information.

Moreover, the quantification of [redacted] by HPLC shows that structure A, n=0 (CAS number [redacted]) is present with [redacted] [Area]% and structure A, n =2 is present with [redacted] [Area]% while all other constituents are present below [redacted] [Area]% and as such does neither correspond to the composition as reported in section 1.2 of the dossier nor to the compositions of [redacted].
Taking into account that a significant part of the composition of the registered substance differs between [redacted] as such, and that the information given on the composition refers both to a well-defined substance and to a UVCB substance, ECHA concludes that the reported composition in section 1.2 of the dossier is not appropriate and has not been provided to the required level of detail.

You are accordingly requested to provide the detailed 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. You shall specify the identity and typical, upper and lower concentration level of each of the constituents and groups of constituents required to be reported according to the following principles.

I. <u>Well-defined substances</u>
If the substance subject to this registration is a well-defined substance you shall amend the compositional information reporting the main constituent(s) and any impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance in accordance with the conventions specified in Chapter 4.2 of the Guidance.

II. <u>UVCB substances</u>
If the substance subject to this registration is a UVCB substance you 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, you 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 you cover individual compositions obtained from different manufacturing process conditions, you shall report separately the starting materials, manufacturing process and each composition that covers the same substance.

More generally, you should note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations. As already explained under the previous section, 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.

Regarding how to report the composition in IUCLID, please note that the technical details on how to report the composition of well-defined substances and UVCB substances in IUCLID are available in section 9.4.2 of the Manual: How to prepare registration and PPORD dossiers in IUCLID 6 for registration under REACH (version 1.0, April 2016) on the ECHA website. You shall follow these technical details.

You 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.

In your comments to the draft decision you outlined you intend to address the information requirement, composition of the substance (Annex VI, Section 2.3). Irrespectively of whether the newly provided information may be sufficient to meet the information requirement addressed in the decision, ECHA can already point out the following:

- You should note that the 'boundary' composition would be expected to cover all co-registrants and not only those of ERRC. Furthermore, you (as lead registrant) should provide your own composition(s) with the typical concentration and concentration ranges for each constituent.
- You should further note that the structures of [redacted] and [redacted] contain chiral centers. As already explained above, [redacted] and [redacted] and those referred to as impurities, e.g. [redacted] do not describe individual constituents but represent a group of constituents (stereo-isomers). Therefore, depending on the concentration of each isomer it is unclear whether each will be >10% and <80% to be considered as multi-constituent substance.
- You included the comment "[redacted] *as decribed above* [redacted]" (see point 2.) on page 4 of the document "[redacted]"), which is confusing as resins containing [redacted]% would contain [redacted]% of other constituents. It is unclear how these compositions will be registered and whether these resins, depending on the different other constituents and their respective concentrations fulfil the polymer definition or not. Furthermore, assessing the polymer status of these substances must be determined based on their overall composition. When a substance does not meet the polymer definition even though it includes polymeric constituents, the registration obligations apply to that substance. In addition, the concentration range of [redacted]% is not part of the 'boundary' composition as suggested in the provided table of the same document. It is further unclear whether you (as lead registrant) manufacture a resin with this concentration range.
- Given the fact that resins with either [redacted] seem to be manufactured, no information is provided how the process is controlled to obtain these different compositions. While you stated that resins with [redacted]% are polymers because of the high oligomeric content, it is unclear why compositions with [redacted]% would not.
- 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. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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 11 March 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 requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

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

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 2015.

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.