ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 4 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347529-39-01/F
Substance name: Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol
EC number: 500-006-8
CAS number: 9003-36-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 02 October 2012
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 or other identifiers (Annex VI, Section 2.1.) of the registered substance;**
   - **EC and/or CAS entry**

2. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Concentration range values**

3. **Description of the analytical methods (Annex VI, Section 2.3.7) of the registered substance;**
   - **Identification and quantification of the impurities**

You are required to submit the requested information in an updated registration dossier by **13 February 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 requirement(s) 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.

Appendix 1: Reasons

IDENTIFICATION 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 identifier of the substance (Annex VI, Section 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement. According to chapter 4.2.2 of the 'Guidance for identification and naming of substances under REACH and CLP' (June 2016, Version 1.4), referred thereafter as "the Guidance" a multi-constituent substance is a substance in which at least two constituents are present with >10% and <80% respectively.

In section 1.1 of the IUCLID dossier you have selected "multi constituent substance" as substance type. This is in line with section 1.2 of your IUCLID dossier, where each of the three main constituents present at a concentration between 10 and 80% (w/w) were reported, and ECHA agrees that the substance subject to the present decision is best described as a multi-constituent substance. However, the identifiers used in the dossier and in particular the chemical name (Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol), EC number (500-006-8), and CAS entry (9003-36-5) refer to a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials).

A multi-constituent substance, such as the one subject of this registration, should be named as a reaction mass of the main constituents of the substance, as indicated in chapter 4.2. of the Guidance.

According to the Guidance, the generic format to name a multi-constituent substance should be: "Reaction mass of [names of the main constituents]", where only main constituents typically ≥10% contribute to the name. As you described the substance as "Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol" you omit the main constituents of the substance. Therefore ECHA concludes that you did not provide appropriate information on the naming of the substance as required under Annex VI Section 2.1 of the REACH Regulation.

In line with the observation above you are accordingly requested to revise the chemical name assigned to the registered substance. It is recommended that the names of the constituents are presented in alphabetical order and they are separated by the conjunction "and". In principle, the names should be given in English language according to the IUPAC nomenclature rules. Other internationally accepted designations can be given in addition.

Based on the information currently contained in the dossier, ECHA invites you to consider if a chemical name such as "Reaction mass of 2,2'-[methylenebis(4,1-phenyleneoxymethylene)]dioxirane and [2-({2-[4-(oxiran-2-ylmethoxy)benzyl]phenoxy}methyl)oxirane and [2,2'-[methylenebis(2,1-phenyleneoxymethylene)]dioxirane" would be appropriate for the identification of the registered substance.

You shall also delete the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance.

As for the reporting of the information in IUCLID, you shall include the revised information in the reference substance assigned in IUCLID section 1.1.

Further technical details on how to report the identifiers of multi-constituent substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

You shall note that the registration is currently linked to the EC number 500-006-8 which refers to the chemical name "Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol". However, for technical reasons, at this stage you cannot remove or modify the EC number, because the registration is linked to that number in REACH-IT. To ensure unambiguous identification of the registered substance, you shall however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 500-006-8 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 shall also specify, in the same "Remarks" field, any available and appropriate EC or List number for the 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.

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 you with this registration. Should the information submitted by you 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 you in due time as to when 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.

In the comments to the draft decision according to Article 50(1) you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise the Section 1.1 of IUCLID and address the information requirement in an update of the registration. ECHA notes such information, including the adequacy of the proposed new name of the substance, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance identity information requested in this decision has been submitted.

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.

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 4.2 of the Guidance, 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 or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In section 1.2 of the technical registration dossier you reported the compositional information for the substance with a typical concentration value for each constituent. The concentration range values are missing for all constituents. Furthermore each main constituent was reported with IUPAC name, molecular formula, molecular weight range, SMILES notation and structural formula that are contradictory to the provided reference substance name and to the information provided in section 1.4.

Because of the missing concentration ranges and contradictions to the reference substance name and information in section 1.4, your registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity.

Pursuant to Article 41(1) and (3) of the REACH Regulation, you are accordingly requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of.

You shall provide the concentration ranges values for all the constituents reported in the composition of the substance.

You shall as well revise the IUPAC name, molecular formula, molecular weight range, SMILES notation and structural formula for each main constituent, so that they are representative of your substance and consistent with each other. In addition, you shall ensure that there is sufficient analytical information included in section 1.4 of the IUCLID dossier to identify and quantify the substance and to verify the information in IUCLID section 1.2.

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

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 substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

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

In the comments to the draft decision according to Article 50(1) you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise the Section 1.2 of IUCLID and address the information requirement in an update of the registration. In your comments you also provided information on the constituents of the substance. ECHA notes such information will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance identity information requested in this decision has been received.

3. Description of the analytical methods (Annex VI, Section 2.3.7.)

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

You reported a description of a ^{13}C-NMR analysis for quantitative analysis of the constituents (file "[redacted]"). In such analysis you determined the relative amount of the three isomers of the bisphenol F derivatives (i.e. the o-o, p-p, and o-p regioisomers) and the values calculated for each isomer were then reported in the compositional information provided in IUCLID section 1.2 ([redacted]% (w/w) for the o-o isomer, [redacted]% (w/w) for the p-p isomer and [redacted]% (w/w) for the o-p isomer, in addition to [redacted]% (w/w) for bisphenol A derivatives).

ECHA acknowledges that quantitative NMR analysis may be feasible for the determination of the composition. However, in this particular case the quantification results obtained by the ^{13}C-NMR analysis are not confirmed and supported by the results of the HPLC analysis. In fact, the HPLC results show the presence of some impurities present at >1% (w/w), which were not identified neither quantified by NMR. Such impurities are not reported in the composition in section 1.2. In addition, the identification of the peaks in the HPLC was not provided.

Therefore it is not possible to get a clear quantification of the different constituents/groups of constituents of the registered substance. Consequently ECHA concludes that you 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.

In line with Annex VI Section 2.3.7 you are accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents/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.

You should note that ECHA will consider any method that is suitable to verify the composition, including any indirect method involving chemical derivatisation of the substance or any analysis involving also considerations on the starting materials and the manufacturing process.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4. You shall ensure that the composition reported in the dossier according to Annex VI section 2.3. is consistent with the analytical results obtained.

In the comments to the draft decision according to Article 50(1) you have agreed with the information requirements in the draft decision. In addition, you have indicated your intention to revise the Section 1.4 of IUCLID and address the information requirement in an update of the registration. ECHA notes such information will be examined by ECHA only after the deadline set in the adopted decision has passed.

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.

Pursuant to Article 42(1) of the REACH Regulation, ECHA has examined the information you submitted in consequence of an earlier compliance check decision (dated 4 July 2012, CCH-D-0000002320-90-03/F) under Article 41(1) of the REACH Regulation concerning your registration dossier for Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol (EC number: 500-006-8). ECHA consequently considers that the present decision is necessary.

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.
In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) 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 2018.

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.