EUROPEAN CHEMICALS AGENCY

Helsinki, 7 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347526-45-01/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: 21 August 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. **Composition (Annex VI, Section 2.3.) of the registered substance;**

2. **Name(s) or other identifier of the substance (Annex VI, Section 2.1.);**
   - **Manufacturing process**

You are required to submit the requested information in an updated registration dossier by **14 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. 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.

'Guidance for identification and naming of substances under REACH and CLP' (Version 1.4 - June 2016) , referred thereafter as the Guidance, clarifies the difference between well-defined substances and UVCB substances. As specified in the Guidance, chapter 4.1: substances can be divided into two main groups:

1. "Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2.

2. "UVCB substances": Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified by the above parameters.

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.

According to chapter 4.3 of the Guidance, for UVCB substances, 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

- Other 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 if the substance is well-defined or UVCB.

ECHA notes that in section 1.1 of the IUCLID dossier, you identified your substance as a 'UVCB' substance type. In section 1.2 of the IUCLID dossier you have reported two compositions. In the first listed composition ([redacted]), you reported three main constituents, namely:

[redacted]

each with a concentration range between ≥10% and <80% (w/w). These three constituents typically account for [redacted]% of the composition of the registered substance.

In the second listed composition ([redacted]), there is a relatively large number of reported constituents (more than 10), including constituents (mostly oligomers) that are not present in the first listed composition. Furthermore, in section 3.1 you reported two different manufacturing processes relative to the two compositions.

As explained above, the Guidance clarifies the difference between well-defined substances and UVCB substances.

ECHA observes that the first listed composition ([redacted]) is related to a well-defined substance consisting of three main constituents. On the contrary, the second composition is in line with the definition of a UVCB substance.

ECHA therefore concludes that, based on the information in section 1.2 and 3.1, the two reported compositions refer to different substances under REACH. As far as Article 5 of the REACH Regulation requires that "substances [...] shall not be manufactured in the Community or placed on the market unless they have been registered" in accordance with the registration provisions under REACH, the present dossier can only cover one substance.

You are accordingly requested to clarify the composition of the registered substance covered by this registration. In that respect, ECHA foresees two possibilities:

I. If you consider that the substance subject to this registration is the well-defined substance identified by the first listed composition (i.e. [redacted], you should update the dossier by removing the information relative to the second listed composition in section 1.2.

II. If you consider that the substance subject to this registration is the UVCB substance identified by the second listed composition (i.e. [redacted]), you should update the dossier by removing the information about the first listed composition in section 1.2.

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 removing the composition that relates to a UVCB substance. ECHA notes that such information, including the compositional details attached to your above-mentioned comments, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted.

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

ECHA notes that you 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.

According to the Guidance, the description of the manufacturing process shall include information on the chemical identity of the starting materials and information on the most relevant steps of the process.

ECHA observes that the description of the manufacturing process is not sufficiently detailed for the identification of the registered substance. More specifically, in IUCLID section 3.1 you provided two different manufacturing processes. For both manufacturing processes you did not provide information on the ratio of the reactants and on the manufacturing process parameters which can determine the composition of the registered substance and therefore its identity.

Therefore, ECHA considers that you did not provide sufficient information on the manufacturing process description to allow for an accurate and complete identification of the registered substance.
You are accordingly required to provide details of the manufacturing processing steps that are applied to the starting materials. The information submitted must at least include the following:

- The molar ratio between the different starting materials used.
- For each step, all relevant process parameters, such as temperature and pressure, that affect the composition and therefore the identity of the substance.

Furthermore, as indicated in the above section (Composition of the registered substance), and as explained in Chapter 4.3 of the Guidance, the description of the manufacturing process is a main identifier for UVCB substances and therefore a change in the relevant process circumstances would be likely to lead to a different substance that should be registered separately. A manufacturing process may be considered different when the relevant processing steps and/or processing parameters are different. You shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

You are accordingly requested to clarify the manufacturing process of the registered substance covered by this registration. In that respect, ECHA foresees two possibilities:

I. If you consider that the substance subject to this registration is the well-defined substance identified by the first listed manufacturing process (i.e. [redacted]), you should update the dossier by removing the information relative to the second listed manufacturing process in section 3.1. Furthermore, in section 1.1 you should indicate that the type of substance is a well-defined 'multi-constituent' substance. In line with the observation above you should accordingly revise the chemical name assigned to the registered substance. You shall ensure that the chemical name is representative of the specific substance which is the subject of this registration. Based on the information currently contained in section 1.2 for the composition indicated as [redacted], ECHA invites you to consider if a chemical name such as

"[redacted]"

would be appropriate for the identification of the registered substance.

You shall revise the structural formula for the reference 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 chapter 9.4.2 of 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 "[redacted]". You can however not remove or modify at this stage the EC number for technical reasons, because the registration is linked to that number in REACHIT.

To ensure unambiguous identification of the registered substance and in case the name provided in the registration dossier is not appropriate, you shall indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 215-635-0 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". 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 his obligation to fulfil the requirements specified in this decision.

II. If you consider that the substance subject to this registration is the UVCB substance identified by the second listed manufacturing process (i.e. [redacted], you should update the dossier by removing the information about the first listed manufacturing process in section 3.1.

In the comments on 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 Sections 1.1 and 3.1 of IUCLID and address the information requirement in an update of the registration. You have also proposed a new name for the substance in line with ECHA's proposal above.

ECHA further notes, that in your comments you indicated that the registered substance will be defined as "well-defined substance". ECHA notes that such information, including the adequacy of the proposed substance name and other identifiers, will be examined by ECHA only after the deadline set in the adopted decision has passed and all the information requested in this decision has been submitted. However, ECHA agrees that if your substance indeed is a "well-defined substance", then you need to comply with all the above requests addressing "well-defined substances".

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.
In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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 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.