ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 7 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114348227-48-01/F
Substance name: 2-[4-[2-[4-(2-hydroxyethoxy)phenyl]propan-2-yl]phenoxy]ethanol
EC number: 500-082-2
CAS number: 32492-61-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10.05.2013
Tonnage band: 100-1000 tonnes per annum

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 identifier of the substance (Annex VI, 2.1.);**

2. **Composition of the substance (Annex VI, Section 2.3.);**

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

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

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.

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 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. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported. The information provided on the naming and identifiers of the registered substance must be consistent.

You assigned the EC identifier 500-082-2 referring to "[redacted]" to the registered substance. Such identifier refers to a UVCB substance consisting of a multitude of constituents showing a [redacted] structure bound to a number of [redacted] units which distribution on the [redacted] structure is variable in number and symmetry.

For supporting the identity of the registered substance you provided two sets of analytical data referring to two different samples. One set of data, referring to the sample "[redacted]", includes the result of a gas chromatographic analysis showing that the composition of the substance includes constituents differring on the number of [redacted] units bound to the [redacted] structure and also in relation to the symmetry of the distribution of these units. These data are therefore consistent with the identification of the registered substance as of UVCB.

However, the substance identity information as currently reported in the registration dossier is not limited to a UVCB substance. In particular, ECHA notes the following:

- You provided the IUPAC name [redacted] for the registered substance. Such name refers to a well-defined mono-constituent substance including one main constituent present to at least [redacted]%(w/w) and which structural formula shows two [redacted] units attached to a [redacted] structure.

- As mentioned above, the analytical data submitted in the registration dossier have been recorded on two different samples. One set of data referring to the sample "[redacted]" includes a LC-UV chromatogram showing one main peak with area percent corresponding to ca. [redacted]%. The chromatogram shows also other peaks that have been identified by you, among these; one has a peak area percent corresponding to ca. [redacted]%. The composition of the substance from which this sample originates is therefore expected to be known.

According to chapter 4.3 of the Guidance, such a substance should normally be identified as a well-defined substance including in its composition a main constituent (showing a structure with two [redacted] units attached to a [redacted] structure) present at a concentration level ≥ 80%. This substance could be considered as a different substance than the UVCB substance "[redacted]", unless the inherent variability in the composition is relatively large or poorly predictable. ECHA notes that you did not provide information on the manufacturing process of the registered substance, the registration therefore does not include any indication that the composition of the substance varies significantly or unpredictably under given manufacturing process conditions.

- ECHA notes that the information provided on the composition of the registered substance does not clarify whether you intend to register the UVCB substance or the mono-constituent substance.

- Furthermore you reported CAS number ([redacted]) and CAS [redacted] for the registered substance. ECHA notes that this CAS information includes a reference to "poly" in the name and indicates the wording "polymer" in its description. Such an entry may cover substances obtained from a polymerisation reaction that may fulfil the definition of polymer set in the REACH Regulation. This means that if the registered substance is a UVCB substance this CAS entry is not sufficiently specific and does not sufficiently describe the registered substance.
  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), this CAS number [redacted] is linked to the EC entry [redacted] also assigned to the registered substance.

  You 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". As mentioned above 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.

Based on the substance identity information currently included in the registration dossier, ECHA therefore concludes that the chemical identifers as described above are not referring to the same substance. The IUPAC name describes a well defined mono-constituent substance, while the EC identifier a UVCB substance. The CAS identifier is not appropriate for identifying the registered substance, neither as a UVCB substance nor as a well defined substance.
Therefore you are requested to clarify this inconsistency by selecting the correct substance type and the corresponding chemical identifiers for the registered substance. ECHA foresees two possibilities:

(i). If the substance subject to this registration is the UVCB substance "[redacted]", you shall

- Revise the IUPAC name currently specified under the relevant headers of the reference substance in IUCLID section 1.1. You shall ensure that the chemical name is representative of the specific UVCB substance which is the subject of the registration.

- Delete the CAS entry from the CAS information for the registered substance and provide instead any CAS number specifically corresponding to the registered substance (if available). If you deem it appropriate, you can however specify the current CAS entry as "related CAS information" for the registered substance.
- Provide a detailed manufacturing process description, including:

    - The identity and molar ratio of all the starting materials used;
    - The description of the manufacturing steps in the order they occur
    - The relevant process parameters applied to control the composition of the manufactured substance (including the parameters determining the level of oligomerisation of the substance);
    - Information on processing steps applied to isolate the manufactured substance and any purification/fractionation steps used.

  Based on the information given in the analytical report ECHA recognises that you may cover different compositions of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, you shall provide an explanation as to why those compositions refer to the same substance. In addition you shall provide the required information on the source, manufacturing process and constituents of each composition.

  The description of the manufacturing process shall include sufficient information and explanation to understand how the composition of the registered substance varies significantly or unpredictably under given manufacturing process conditions.

- Ensure that the analytical data attached in section 1.4 of the IUCLID dossier supports/reflect the information reported in section 1.1 and 1.2 in relation to the identity and composition of the registered UVCB substance.

(ii). If the substance subject to this registration is a well-defined substance, you shall

- Ensure that the chemical name provided for the registered substance is in accordance with the naming conventions specified in chapter 4.2 of the Guidance.
- Delete the CAS entry from the CAS information for the registered substance and provide instead any CAS number specifically corresponding to the registered substance (if available). If you deem it appropriate, you can however specify the current CAS entry as "related CAS information" for the registered substance.
- Revise the selected substance type from UVCB substance to mono-constituent substance or multi-constituent substance, as appropriate.
- Ensure that the analytical data attached in section 1.4 of the IUCLID dossier supports/reflect the information reported in section 1.1 and 1.2 in relation to the identity and composition of the registered well-defined substance.

Note on the EC identifier:

You shall note that the registration is currently linked to the EC number referring to 500-082-2. Should the substance intended to be covered by this registration refer to a different substance, you can however not remove or modify at this stage the EC number for technical reasons, the registration being 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 500-082-2 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 number for the substance.

You 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 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.

Regarding how to report the information in IUCLID:

- The chemical name shall be indicated in the "IUPAC name" field in IUCLID section 1.1.
- The description of the manufacturing process of the UCVB substance shall be included in the "Description" field in IUCLID section 1.1.
- The CAS number and CAS name shall be reported under the "CAS information" header in IUCLID section 1.1. The current CAS entry can be reported in the "related CAS information" field.

You shall ensure that the chemical name, the identifiers and the manufacturing process description to be reported according to Annex VI, Section 2.1 of the REACH Regulation are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3 of the REACH Regulation.

2. Composition of the substance (Annex VI, Section 2.3.)

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.

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 that respect, according to chapter 4.3 of the Guidance, for UVCB substances, you shall note that 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;

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 regardless of the substance type.

In the composition section of the IUCLID dossier, you reported the presence of [redacted]% of a reference substance showing the same chemical name, EC and CAS identifiers as reported in section 1.1 for the registered substance. Further subdivision of the composition of the substance in terms of the concentration levels of its constituents or groups of constituents, i.e. breakdown of the composition, has not been included in section 1.2 of the IUCLID dossier.

As described under point 1 of Appendix 1 of the present decision, the analytical data attached to the IUCLID dossier show that more specific information on the composition of the registered substance is known to you. Indeed you identified and quantified constituents/ groups of constituents present in the composition of the analysed samples. In particular, information on the variability of the concentration levels of the constituents/groups of constituents present in the composition of the registered substance is missing.

ECHA therefore concludes that not all known constituents have been identified and reported individually. Consequently, the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity (see Annex VI, section 2.3).

You are accordingly requested to revise the composition of the registered substance.

If the substance subject to this registration is a UVCB substance you shall:

- Report all known constituents and all constituents present at concentrations ≥ 10%.
- Identify and report all constituents that are relevant for classification and/or PBT assessment independently from their concentration.
- Report unknown constituents as far as possible by a generic description of their chemical nature. Regarding the reporting of the oligomeric constituents a distinction according to the degree of oligomerisation is considered appropriate as a baseline.

If the substance subject to this registration is a well-defined substance you shall:

- 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.
- Provide the chemical identity of the impurities and/or additives (≥ 1%).

Regarding how to report the composition in IUCLID, the following applies: you 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, 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 UVCB and well defined substances in IUCLID are available in paragraph 2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) which is available 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 ensure that the information on the composition of the substance is verifiable and therefore supported by a description of the analytical methods used for its identification, as required under Annex VI section 2.3.7. of the REACH Regulation. Consequenty, you will need to report only the analytical data of the substance in section 1.4 that is described by appropriate and consistent chemical identifiers in section 1.1.

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 7 December 2015.

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 request(s) and the deadline.

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 draft 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.

4. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is in the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.