ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 28 October 2016

Addressee: [redacted]

Decision number: CCH-D-2114347165-51-01/F
Substance name: Pyridinium, 1-(phenylmethyl)-, ethyl methyl derivs., chlorides
EC number: 272-695-0
CAS number: 68909-18-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19.08.2011
Registered tonnage band: 100-1000T

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**

2. **Composition (Annex VI, Section 2.3.)**

3. **Description of the analytical methods (Annex VI, Section 2.3.7) of the registered substance;**

You are required to submit the requested information in an updated registration dossier by **5 May 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.

Appeal

Applicable only for the final decision: 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 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.

Appendix 1: Reasons

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

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 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) a detailed description of the manufacturing process and (2) the chemical name, 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.

(1) Description of the manufacturing process

The alkyl pyridines starting material used to manufacture the registered substance has not been identified to a sufficient level of detail and the information provided on it in the dossier is not fully consistent. This information is essential for the identification of the registered substance and the reasoning for that is explained below.

The chemical structure of the alkyl pyridines reported in the "[redacted]" indicates that these pyridines are potentially penta- substituted. Additionally, the Registrant indicates that the substituents can be of alkyl, aminoalkyl, alkenyl etc. type, which in fact represent large group of different chemicals.

In contrast to this information, products identified by the qualitative analysis (as shown in Fig 12 of the "[redacted]") are derived from either bi- or tri-substituted pyridines.

Furthermore in section 10.4 of the analytical report the Registrant provided qualitative information on the structural types that may be potentially present in the starting materials, including substituted pyridines and acetamides. However, no quantitative information on the starting material is provided.

ECHA points out that UVCB substance such as the alkyl pyridines used as starting materials cannot be sufficiently identified by a chemical name and CAS/EC numbers only. As the composition of such starting material is to a significant extent known and is one of the factors determining the composition of the registered substance, compositional information of that starting material (in terms of identity and upper and lower concentration levels of the individual poly-substituted pyridines, that could be grouped into structurally related groups, like mono-alkyl pyridines, di-alkyl pyridines, alkyl-alkenyl pyridines, di-alkenyl pyridines, etc.) is a necessary element for its identification and therefore for the identification of the registered substance itself. In addition, quantitative information on the starting material is essential for the identification of the registered substance.

Therefore ECHA concludes that insufficient information is given on the manufacturing process in relation to the type of substituents present on the pyridine ring. More specifically, in order to complete the information on the manufacturing process description, the Registrant shall provide more detailed compositional information of the starting material in terms of identity and upper and lower concentration levels of the individual poly-substituted pyridines.

(2) Chemical name and other identifiers

The Registrant did not provide a chemical name in the IUPAC name field of section 1.1. Furthermore, the Registrant highlighted in the analytical report attached in section 1.4 that "CAS number assigned to [redacted] for pre-registration [redacted] ([redacted]: EINECS number [redacted]) is too specific." and that "CAS number [redacted] ([redacted]) is more appropriate and should be adopted for [redacted].".

However, ECHA notes that the proposed new CAS number [redacted] seems not to fully match the chemical identity of the substance as it only refers to alkyl derivatives of 1-phenylmethyl pyridine, while the composition and analytical report reveals that alkyl chains also bear some functional groups.

In line with the observations above, the Registrant is accordingly requested to provide a representative chemical name of the registered substance and corresponding identifiers, reflecting the presence of functional groups in the alkyl chains in the registered substance.

As for the reporting of the information in IUCLID, the chemical name and manufacturing process description shall be specified in the "IUPAC name" and "Description" field in IUCLID section 1.1, respectively. The CAS entry (if available and appropriate) for the registered substance) should be reported in the " "CAS information" header of the reference substance in IUCLID section 1.1. The CAS entry with CAS number 68909-18-2 may be reported under the "Related CAS information" header in IUCLID section 1.1.

When the EC and CAS identifiers do not fully correspond to the registered substance, the Registrant shall ensure to delete the CAS information and indicate in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 272-695-0 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". The Registrant should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. The qualitative analytical information provided in the dossier confirms that the EC and CAS identifiers used may not be representative for the registered substance.

The Registrant should note that ECHA has established processes, 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. Should the Registrant consider that the EC identifier provided in his dossier should be adapted to cover a different substance or if it actually covers several other substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

The Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

2. Composition (Annex VI, Section 2.3.)

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contain sufficient information for establishing the composition of the registered substance and therefore its identity.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

In that respect, according to chapter 4.3 of the Guidance 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 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 by a generic description of their chemical nature.

In the present dossier, the Registrant listed in section 1.2 of the IUCLID dossier a multitude of constituents, of which only 8 constituents are fully characterized, 32 remain 'unassigned' and 39 have a 'proposed structure'. For each of these constituents only the typical concentration is provided with the value of "<[redacted]%". As indicated in section III.A.3 below, the composition listed in section 1.2 was derived based on the qualitative analysis.

While the presence of unassigned or proposed constituents could be understood for a complex UVCB substance, the absence of concentration range for listed constituents (including the fully characterized ones) does not allow verification of the substance composition, and therefore its identity.

ECHA therefore concludes that the compositional information provided in section 1.2 is incomplete and not verifiable, as it is not supported by the quantitative analytical data. The Registrant is therefore requested to report the representative concentration ranges and typical concentration for all constituents listed in section 1.2, based on a quantitative analysis.

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. For the practical reasons, constituents present at <10% may be grouped, based on their structural similarity (e.g. mono-alkyl pyridines, di-alkyl pyridines, tri-alkyl pyridines, tetra-alkyl pyridines, etc. could be reported as groups of constituents). The information on the composition should be verifiable by the qualitative and quantitative analytical methods.

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: 2.0, July 2012) on the ECHA website.

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

ECHA notes that the Registrant has not provided sufficient analytical data, including description of analytical methods, as required for the identification and quantification of the registered substance per Annex VI section 2.3.7.

More specifically, the Registrant provided report of the analysis ("[redacted]") in section 1.4 of the dossier with a qualitative GCMS/LCMS data including structural characterization of some constituents. However, a quantitative analysis was not provided, hence the submitted information cannot be used to define the concentrations of the identified constituents and therefore it cannot support the composition of the registered substance, as reported in section 1.2.

Furthermore, the substance is indicated as a chloride, however no quantitative analysis that could verify the content of chloride in the substance was provided. This information is necessary to confirm the identity and composition of the registered substance.

ECHA therefore concludes that the information has not been provided to the required level of detail.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the description of the analytical methods used for the quantification of the registered substance and constituents /groups of constituents required to be reported in the composition of the registered substance, as indicated in section III.A.2 below. The description shall also include information on the method used to quantify the chlodride content.

Regarding how to report the description of the analytical methods, the information shall be attached in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for recording the spectra is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation. For chromatographic methods, the method description information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent/group of constituents.

The Registrant shall ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results obtained.

Appendix 2: Procedural history

The compliance check was initiated on 22 March 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

On 17 May 2016 ECHA notified you of the draft decision and invited you to provide comments. You did not provide comments within the timeline indicated by ECHA.

On 8 September 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 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. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. 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.