ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306140-72-01/F Helsinki, 10 August 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Formaldehyde, oligomeric reaction products with phenol and m-phenylenebis(methylamine), CAS No 57214-10-5 (EC No 500-137-0), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for Formaldehyde, oligomeric reaction products with phenol and m-phenylenebis(methylamine), CAS No 57214-10-5 (EC No 500-137-0), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

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

The compliance check was initiated on 03 December 2014.

On 24 April 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 1 June 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision and indicating the Registrant's intention to submit an update of the registration.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 11 June 2015 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 proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, 2.1.);
2. Composition of the substance (Annex VI, 2.3);
3. Spectral data (Annex VI, 2.3.5);
4. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.);
5. Description of the analytical methods (Annex VI, section 2.3.7.).

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **17 November 2015** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity 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, 2.1.)

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) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in section 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" hereinafter. Any other identifier, including any CAS number (if available) and any EC number (if available and appropriate) for the substance shall also be reported.

(i). The description of the manufacturing process

According to the chemical name assigned by the Registrant to the registered substance, this registration refers to an oligomeric substance obtained by reacting formaldehyde with both phenol and m-phenylenebis(methylamine). The Registrant indicated in section 3.1 of the

IUCLID dossier that the registered substance is "[redacted]"
at elevated temperature. No further information on the manufacturing process was reported in the dossier.

ECHA however considers that the description of the manufacturing process is not sufficiently detailed to unambiguously identify the registered substance. In particular, the following information is missing:

- The ratio of reactants (formaldehyde, phenol and m-phenylenebis(methylamine));
- The order of the reaction steps with phenol and m-phenylenebis(methylamine) (sequential or simultaneous). ECHA underlines that it is unclear from the current description if formaldehyde is first oligomerised with phenol before the reaction with m-phenylenebis(methylamine) takes place or if phenol and m-phenylenebis(methylamine) react simultaneously with formaldehyde;
- The process parameters used to control the composition of the substance, including the degree of oligomerisation.

As the abovementioned missing elements of the manufacturing process are expected to determine the composition of the registered substance, and taking also into account the limited information on the composition of the registered substance in the current dossier, ECHA considers that these elements are necessary for the identification of the substance.

The Registrant is accordingly required to provide details of the manufacturing processing steps that are applied to the starting materials. The information submitted by the Registrant must at least include the following:

- Molar ratio of all the starting materials;
- Description of the manufacturing steps in the order they occur, including any preliminary step, the steps involving chemical transformation as well as the isolation and purification steps carried out for the synthesis. Regarding more specifically the steps involving a chemical transformation, ECHA underlines that the Registrant shall provide a description of the relevant oligomerisation steps, including the parameters used to initiate, propagate and terminate the oligomerisation reactions;
- For each step, all relevant process parameters that affect the composition and therefore the identity of the substance must be provided.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.

The Registrant shall ensure that the chemical name and other identifiers reported in section 1.1 of the IUCLID dossier are consistent with the substance as described by the manufacturing process. In the eventuality that the EC entry with EC number 500-137-0 currently assigned in this registration does not correspond to the substance actually manufactured or imported, the Registrant should note this identifier cannot be removed or modified at this stage for technical reasons, the registration being linked to that number in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however in this situation indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 500-137-0 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 shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Registrant shall note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt 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.

(ii). The CAS number

The Registrant reported the CAS number 57214-10-5 as CAS information for the registered substance. The CAS name for this entry is "Formaldehyde, polymer with 1,3-benzenedimethanamine and phenol". This CAS number 57214-10-5 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 500-137-0 also assigned by the Registrant to the registered substance.

The Registrant 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*". 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.

Accordingly, the Registrant shall delete the CAS number currently specified under the "CAS information" header of the reference substance in IUCLID section 1.1 and report a CAS number specifically corresponding to the registered substance (if available). If the Registrant deems it appropriate, he may specify the current CAS entry 57214-10-5 under the "Related CAS information" header in IUCLID section 1.1 for the registered substance.

Regarding how to report a CAS number corresponding to the registered substance, the information shall be included under the "CAS information" header in IUCLID section 1.1.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration by 31 July 2015. The Registrant is reminded that this decision does not take into account any updates submitted after 24 April 2015. 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, 2.3.)

Annex VI, section 2.3 of the REACH Regulation requires the Registrant to provide the composition of the 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.

ECHA notes that the registration does not contain sufficient 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.

In that respect, according to 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, 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 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 by a generic description of their chemical nature.

For each constituent or group of constituent, the typical, minimum and maximum concentration shall be specified.

ECHA notes that the Registrant did not provide any information on the identity and concentration levels of the constituents or groups of constituents present in the composition of the registered substance. The Registrant instead reported the composition as consisting of [redacted]% of the substance itself, i.e. of the "*Formaldehyde, oligomeric reaction products with phenol and m-phenylenebis(methylamine)*". ECHA underlines that the report from the gas chromatographic (GC) analysis attached in section 1.4 includes information indicating the presence of predominant constituents in the analysed sample and that a resolution of the composition can thus be achieved.

Therefore ECHA concludes that the information provided on the composition has not been provided to the required level of detail.

The Registrant is accordingly requested to specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported. Concerning the reporting of the unknown constituents, the Registrant shall note that, for substances such as the registered substance, a subdivision of these unknown constituents according to the degree of oligomerisation is necessary for this purpose as a baseline. For each group of unknown oligomeric constituents, information on the relative content of formaldehyde, phenol and m-phenylenebis(methylamine) units shall be specified.

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, shall be reported in the appropriate fields in IUCLID. For the unknown 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 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).

ECHA highlights that the Registrant shall also ensure that the compositional information is verifiable and therefore supported by qualitative and quantitative analytical data, as required under Annex VI section 2.3.7. 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.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration by 31 July 2015. The Registrant is reminded that this decision does not take into account any updates submitted after 24 April 2015. 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.

3. Spectral data (Annex VI, 2.3.5);

"Spectral data" (ultra-violet, infra-red, as well as nuclear magnetic resonance (NMR) or mass spectrum) is an information requirement as laid down in Annex VI, section 2.3.5 of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant attached the required set of spectra in the registration dossier.

However, regarding at least the submitted proton NMR spectrum, ECHA notes that the Registrant assigned certain NMR peaks to protons from a "benzyl alcohol" moiety. Benzyl alcohol is reported neither in the composition nor in the description of the manufacturing process. The origin of this moiety cannot be explained by the reactions expected to take place between the formaldehyde, phenol and m-phenylenebis(methylamine) reactants used for the manufacturing. ECHA notes that the analysed sample is presented in the report as a curing agent. ECHA is aware that substances such as benzyl alcohol may be used as a component (e.g. non-reactive diluent) in the formulation of products used for curing applications. However ECHA cannot exclude that the "benzyl alcohol" moiety belongs to the composition of the registered substance. Therefore it is not clear how the provided NMR relates to the registered substance.

Accordingly, the Registrant is requested to clarify the origin of the peaks originating from the "benzyl alcohol" moiety. If the sample used for the NMR analysis does not refer to the registered substance on its own (e.g. if the "benzyl alcohol" moiety detected on the NMR spectrum does not fully belong to the composition of the registered substance), the NMR spectrum should be replaced by a spectrum recorded on a sample of the manufactured substance on its own.

As for the reporting of the NMR data in the registration dossier, the information shall be included in IUCLID section 1.4.

The Registrant shall ensure that the name and other identifiers for the registered substance as well as the composition reported in the dossier are consistent with the structural information derived from the NMR spectrum of the registered substance. In particular, if the presence of the benzyl alcohol in the composition of the registered substance is confirmed by the analytical data, the Registrant is accordingly requested to revise the composition reported in IUCLID section 1.2 to take also into account the presence of that constituent. The source for the presence of that constituent shall also be reflected in the description of the manufacturing process and in the chemical name, CAS number and EC number to be assigned to the registered substance.

The Registrant shall also ensure that the identification of the registered substance is based on the information for the substance as such and not the substance in a mixture. Regarding more specifically the contribution of the solvent used in the manufacturing process of the registered substance, the Registrant shall note that the quantity of such solvent which can be removed from the substance without affecting its stability or changing its composition

shall not be included in the mass balance.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration by 31 July 2015. The Registrant is reminded that this decision does not take into account any updates submitted after 24 April 2015. 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.

4. High-pressure-liquid chromatogram or gas chromatogram (Annex VI point 2.3.6.)

High-pressure-liquid chromatogram or gas chromatogram (GC) is an information requirement as laid down in Annex VI, section 2.3.6 of the REACH Regulation.

The Registrant attached a copy of a chromatogram from a GC analysis to the dossier.

However, ECHA observes that the Registrant did not provide a complete report from the chromatographic analysis. In particular, a peak table listing all the peaks detected with the corresponding peak area has not been included. ECHA points out that this information is required since it constitutes a numerical representation of the chromatogram.

Accordingly, the Registrant is requested to provide the chromatogram including the report from the chromatographic analysis of the registered substance.

As for the reporting in the registration dossier, the information shall be included in IUCLID section 1.4.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration by 31 July 2015. The Registrant is reminded that this decision does not take into account any updates submitted after 24 April 2015. 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.

5. Description of the analytical methods (Annex VI, section 2.3.7.)

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

The Registrant submitted a copy of a copy of GC chromatogram which shows the existence of at least 6 constituents or groups of constituents. Whilst the analytical technique may be used for the identification and quantification of the constituents, the report from the GC analysis does not provide any information on the identity and concentration levels of the constituents in the substance.

The Registrant is therefore requested to provide a 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. 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.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4.

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

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration by 31 July 2015. The Registrant is reminded that this decision does not take into account any updates submitted after 24 April 2015. 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.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[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.