ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114321158-56-01/F Helsinki, 11 March 2016

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

**For SF Resin, EC No 447-830-3 (CAS No NS), 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 SF Resin, EC No 447-830-3, submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirement[s] 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 30 September 2015, i.e. 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 13 January 2015.

ECHA notified the draft decision to the Registrant and invited them to provide comments. ECHA took into account the comments, which were sent within the commenting period, and they are reflected in the Sections III.A.1 and III.A.2.

On 21 January 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 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. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, section 2.3.7)
2. Composition of the substance (Annex VI, section 2.3)

**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 20 June 2016 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. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, section 2.3.7)

The "Description of the analytical methods or the appropriate bibliographical references for the identification of the substance" is a standard information requirement as laid down in Annex VI, section 2.3.7. of the REACH Regulation. The methods should be adequate to identify and quantify the constituents of the registered substance. The results of these methods should be given and the methods need to be described at a level of detail that allows the reproduction of the results including all necessary calculations.

The registered substance has been analysed using both gas chromatography (reported in the file "GC-MS.pdf") and liquid chromatography (reported in the file "LC-ESI-MS.pdf"). The gas chromatography data reports area percent and identification of the peaks found. The liquid chromatography data is annotated with the identity of the peaks found and does not mention any quantitative evaluation related to the absolute or relative abundance of the constituents present. The Registrant has not explained or justified how the measured area percent relates to the reported mass percent for each constituent found in the gas chromatography data. For the constituents found in LC-MS data no attempt was made to quantify them.

ECHA notes that the relative abundance of the constituents found by different analytical methods has not been considered in the method description. ECHA also notes that no attempt was made to quantitatively analyse the results of the liquid chromatography analysis. Finally, ECHA notes that the relative signal derived with mass spectrometric detection is not necessarily directly related to the relative mass abundance of the respective constituents and further calculation or justification is needed.

ECHA therefore concludes that the analytical methods are not described to an extent that allows reproduction of the quantitative assessment of the raw data.

According to the registrant's comments on the draft decision, the registrant acknowledges the validity of the points raised in the draft decision and highlights the analytical complexity of the registered substance.

The registrant confirms that quantitative analysis using LC-MS data is not feasible for the lack of reference material and quantitative analysis using GC is not feasible as the higher molecular constituents decompose under the analytical conditions. Additional GPC data is offered for the quantitative analysis of the registered substance. This data is by nature of the method not separating individual constituents but groups with similar apparent mass. ECHA acknowledges the analytical complexity of the registered substance and recognises that a complete analytical determination of all constituents of the substance may not be feasible. The registrant shall select analytical techniques suitable and appropriate with respect to the current state-of-the-art and apply them to the qualitative and quantitative analysis of the registered substance. The applied method shall be described as requested below.

The Registrant is accordingly 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 should be sufficient to allow reproduction of the raw results and the calculations necessary for the quantitative assessment of these results.

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

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

The "Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. The composition needs to be consistent with the analytical data reported in section 1.4 and the identification of the registered substance reported in section 1.1 of the IUCLID dossier.

It is stated in chapter 4.3.1.1 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) - referred to as "the Guidance" thereinafter that "for a UVCB substance, all known constituents and all constituents present at concentrations ≥ 10% should be specified by at least an English-language IUPAC name and preferably a CAS number; the typical concentrations and concentrations ranges of the known constituents should be given as well."

ECHA observes that:

- in the reported composition in section 1.2 of IUCLID, typical concentrations of the given constituents are stated for the registered substance but the concentration ranges are omitted;
- the composition reported does not list all constituents reported in the analytical data given in section 1.4 of the IUCLID dossier. While the constituents and area percent reported in the file "GC-MS.pdf" are consistent with the reported composition in section 1.2 of the IUCLID dossier, the results reported in the file "LC-ESI-MS.pdf", which reports the analysis results obtained from the same sample, have not be taken into consideration in the composition.
- The reported constituents are in majority alkylresorcinols and none of the constituents is expected as the outcome of a condensation reaction between [redacted], whereas the registered substance is identified as "[redacted]"

ECHA notes that the registration dossier includes contradictory information regarding the composition of the substance:

- the information presented in the analytical report indicate more constituents than given in the composition in section 1.2 of the IUCLID dossier.
- None of the expected products of the condensation reaction referred to in the name given to the registered substance are reported in the composition.

ECHA further notes that the concentration ranges are missing and the values reported are incorrect considering that the values add up to 100% but some constituents that have been found in the analytical data have been omitted from the composition.

According to the Registrant's comments, the registrant acknowledges the validity of the points raised in the draft decision and highlights the analytical complexity of the registered substance.

ECHA acknowledges the analytical complexity of the registered substance and recognises that a complete analytical determination of all constituents of the substance may not be feasible.

The composition should be reported with the precision and detail that the analytical techniques applies allow for. The analytical techniques shall be selected to be suitable and appropriate with respect to the current state-of-the-art.

In case a direct and complete analytical determination is not possible or disproportionately difficult, it is acceptable to report groups of constituents with related properties that can be determined experimentally and describe the kinds of constituents covered by each group and their relative proportions with the support of additional analytical data and knowledge of the starting material and the chemical processes applied.

For each of the (groups of) constituents the information requested in this decision below be provided.

Therefore the Registrant is required to amend the reported composition such that, for each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified. The concentration range values must be representative for the registered substance as manufactured and in accordance with the analytical data provided in section 1.4 of the IUCLID dossier. All known constituents and all constituents present at concentrations ≥ 10% should be specified.

In addition the composition needs to be consistent with the analytical data reported in section 1.4 and the identification of the registered substance reported in section 1.1 of the IUCLID dossier as "[redacted]". If the Registrant considers necessary to adjust the EC number assigned to the registered substance in the updated dossier, the Registrant is requested to include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons". At this stage, the Registrant should not remove or revise the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update where the EC entry is changed.

Regarding how to report the composition of the registered substance 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: 1.0, June 2010) on the ECHA website.

## 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 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.