EUROPEAN CHEMICALS AGENCY

Final decision: CCH-D-0000002651-79-03/F Helsinki, 29 January 2013

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

For Phenol, methylstyrenated, CAS No 68512-30-1 (EC No 270-966-8), 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 dossier for Phenol, methylstyrenated, CAS No 68512-30-1 (EC No 270-966-8) submitted by [redacted] (Registrant). The scope of the present decision is limited to obligation to submit a CSR pursuant to Article 14 and Annex I of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 2 November 2012, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 2 May 2012.

On 31 July 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 30 August 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 2 November 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

a. Name or other identifier of the substance (Annex VI Section 2.1). The Registrant shall provide sufficient information on the registered substance to enable the substance identity to be determined. The Registrant shall also revise the chemical name of the registered substance, as specified under point III(1)(a) below;
b. Composition of the substance (Annex VI, 2.3.). Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under point III(1)(b) below;
c. The spectral data (Annex VI, 2.3.5.). The registrant shall provide the missing analyses as specified under point III(1)(c) below;

2) Pursuant to Articles 41(1)(a) (c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit the following information:

a chemical safety report ("CSR") for the registered substance.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the required CSR in the form of an updated IUCLID dossier to ECHA by **29 May 2013.**

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 requirement.

1) Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

a) Name or other identifier of the substance (Annex VI Section 2.1. of the REACH Regulation).

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA observes that the Registrant did not provide sufficient information on the name and the description of the substance for its proper identification, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the Registrant specified as chemical name for the substance "Phenol, methylstyrenated". The Registrant shall note that, by describing the result of the reaction as "methylstyrenated", the position of the methyl and vinyl groups remains unidentified. Furthermore, the identity of the specific starting material used has not been provided. Due

to the above mentioned issues the name given "Phenol, methylstyrenated" together with limited information on the starting material used may indicate that the substance does not refer to one specific substance but corresponds to a generic chemical name potentially covering several substances under REACH, including UVCB substances obtained from different manufacturing processes or having different structural representations. For the same reason, the assigned CAS entry with CAS name "Phenol, methylstyrenated" is not an appropriate identifier of the registered substance.

In addition, the description of the manufacturing process reported in IUCLID section 3.1 is not sufficiently detailed to identify the substance. In particular, the relevant process parameters used for its manufacturing, including details of the identify of the starting material, the parameters used to control the degree of polymerisation and information on any processing step applied to isolate the manufactured substance have not all been specified.

The Registrant is accordingly requested to clarify the identity of the registered UVCB substance. For this purpose, the Registrant shall provide a chemical name that is representative of the manufacturing process used. The name shall therefore include details on the specific monomers used as starting materials and clarification on the term "methylstyrenated". The Registrant shall also delete the CAS entry with CAS name "Phenol, methylstyrenated" and assign instead any available CAS information specifically corresponding to the registered substance. The Registrant shall, in addition, provide the missing information on the description of the process used for the manufacturing of the substance registered.

Regarding how to report the chemical name and description of the UVCB substance, the information shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively.

b) Composition of the substance (Annex VI, 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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the specific registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation. More specifically, the Registrant provided only the upper concentration limit for the constituents reported in IUCLID section 1.2 ([redacted]). As the concentration ranges are very broad several substances can be represented by the composition reported in the dossier.

In line with the above, the Registrant is requested to revise the composition information and provide the minimum, maximum and typical concentration for each constituent or group of constituents required to be identified. The Registrant shall ensure that the compositional information solely represents the registered substance and can be used as an identifier for that substance.

Regarding how to report the composition of UVCB substances in IUCLID, further technical information is provided in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010). The Registrant shall also ensure that the information provided on the composition of the substance is confirmed by the required analytical data included in IUCLID section 1.4. The Registrant shall ensure in particular to remove any analytical information

which has not been generated on the substance which is the subject of this registration and replace it with data carried out on the registered substance, as appropriate.

c) The spectral data (Annex VI Section 2.3.5. of the REACH Regulation).

ECHA observes that the registration does not contain any UV or NMR spectral data which is required according to Annex VI Section 2.3.5. of the REACH Regulation to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infrared data. NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts. As all reported constituents contain characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance. UV Spectrum reveals information which is used to obtain factual qualitative evidence of the presence or absence of characteristic chemical functionalities in the composition.

The Registrant is therefore requested to submit a NMR spectrum such as a ^{1}H-NMR or a ^{13}C-NMR and a UV spectrum. Alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme can be provided.

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

2) Missing Chemical Safety Report

Pursuant to Article 10(b) of the REACH Regulation the registration shall include a CSR when required under Article 14, in the format specified in Annex I to the REACH Regulation. Furthermore, pursuant to Article 14 of the REACH Regulation, a chemical safety assessment shall be performed in accordance with Annex I and paragraphs 3 to 7 of Article 14, for all substances subject to registration in accordance with Title II, Chapter 1 of the REACH Regulation in quantities of 10 tonnes or more per year per registrant.

The registration dossier for the registered substances subject to the present decision neither contains a CSR nor does it provide for a valid justification why a chemical safety assessment was omitted and not documented pursuant to Article 14(2) of the REACH Regulation. The Registrant is therefore requested to submit the CSR for the registered substance subject to the present decision.

When documenting the outcome of the chemical safety assessment, the Registrant may use the recent version of the Chemical Safety Assessment and Reporting tool (Chesar, version 1.2), designed to help registrants to carry out their chemical safety assessments and preparing their CSR, available at http://chesar.echa.europa.eu/.

Regarding how to write a CSR or submit a CSR further information is provided in Guidance on information requirements and chemical safety assessment Part F. Chemical Safety Report, version 2, July 2008.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
Director of Regulatory Affairs