EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003430-86-03/F Helsinki, 8 October 2013

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

For Benzene, mono-C10-13-alkyl derivs.,distn. residues, CAS No 84961-70-6 (EC No 284-660-7), 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 Benzene, mono-C10-13-alkyl derivs., distn. residues, CAS No 84961-70-6 (EC No 284-660-7) submitted by [redacted] (Registrant).

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 20 June 2013, 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 from initiating further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 19 December 2012.

On 13 March 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 11 April 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments but did not amend the draft decision.

On 20 June 2013 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

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, 2.1.), as specified under section III.(a) below.
b. Composition of the substance (Annex VI, 2.3.), as specified under section III.(b) below.
c. Description of the analytical methods (Annex VI, 2.3.7.), as specified under section III.(c) below.

Taking into consideration the data currently available in the dossier, ECHA considers the following: Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **8 January 2014.**

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is required to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

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, 2.1.)

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 such as the registered substance should consist of two parts: the chemical name and 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: 1.2, March 2012) - referred to as "the Guidance" hereinafter. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported.

Based on the information provided by the Registrant regarding the composition of the registered substance, ECHA concludes that the exact identity of the individual constituents and groups of constituents are not sufficiently known for the UVCB substance to be identified by its composition alone. A detailed description of the manufacturing process, including the chemical identity of the source and information on the most relevant steps of the manufacturing process, is therefore required.

i. <u>The identity of the source (in terms of identity each individual constituent/groups of constituents) used must be submitted</u>

The identity of the source has not been provided in the Registration dossier. ECHA considers that the composition of the source is one of the factors determining the composition of the registered substance. Identification based on the name and compositional information of that source (in terms of identity of the predominant groups and carbon number range) is necessary for the identification of the registered substance.
The Registrant is accordingly required to specify a representative name and relevant identifiers of the source as well as the identity of each individual constituent or groups of constituents present in the composition of the source. The Registrant shall ensure that the source is specified using a chemical name that accurately reflects its identity.

Further information for the identification and naming of substances, including the source, is available in the Guidance.

ii. <u>The description of the manufacturing processing steps must be submitted by the Registrant</u>

The Registrant has provided only a very generic description of the manufacturing process in section 3.1 of the dossier "[redacted]". However, no further information has been specified on the manufacturing process parameters which determine the composition of the registered substance and therefore its identity.

The Registrant is accordingly required to provide details of the manufacturing processing steps that are applied to the source, in the order they occur. This must include the following:

- Description of each refining step. The information shall be supplemented with details of the reaction mechanisms involved. For instance, where the refining process involves catalytic reactions, the information shall include, for each catalytic reaction, details of the type of catalyst(s) used in terms of reaction(s)that they catalyse (including detailed information on the selectivity of the catalyst towards the reaction products, reaction mechanisms etc.). The information on how the use of the specific catalyst affects the composition of the registered substance must be also included
- Other relevant process steps and parameters
- Distillation parameters – pressure and temperature range must be specified
- An explanation on the chemical origin and relative abundance of the different constituents/ groups of constituents of the registered substance.

For clear illustration the Registrant shall provide a flow chart of the manufacturing process.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, then the detailed description of the manufacturing process required under point ii. hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the processing steps and/or processing parameters are different. The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

Regarding how to report the chemical name and description of the manufacturing process of the UVCB substance, the information shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively. The flow chart should be included in section 1.4 of the IUCLID dossier.

(b) The composition (Annex VI, 2.3)

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 and appropriate 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.

More specifically, ECHA notes that the Registrant only reported a very generic composition "[redacted]% *(w/w) Benzene, mono-C10-13-alkyl derivs., distn, residues*" with some typical structural formulas. However no detailed information was provided on the concentration ranges for the various constituents/groups.

Therefore the Registrant is requested to identify and report individually all constituents present in the substance with a concentration of ≥ 10 % as well as all constituents relevant for the classification and/or PBT assessment of the registered substance. Other constituents shall be identified by a generic description of their chemical nature(e.g. alkyl-benzenes, alkenyl-benzenes, alkyl-indans, alkyl-tetralins,dinaphthyl-benzenes, naphtalenes, diphenyl-alkanes and fluorenes). Furthermore, concentration ranges shall be provided for all identified constituents and groups of constituents. This information shall be reported in IUCLID section 1.2.
The concentration range values must be representative for the registered substance as manufactured and it shall be clarified how the minimum and maximum values for each group of constituents and also for each carbon number were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA is not able to conclude on the representativeness of these values and the identity of the substance covered by the registration shall not be considered valid.

Regarding how to report the composition in IUCLID, the following applies: The Registrant shall report the minimum, maximum and typical concentration of each individual constituent or group of constituents in the appropriate fields in IUCLID. Details of the protocol followed to determine the different concentration values of each constituent /group of constituents shall be provided in the Remarks field of the corresponding repeatable block for that group. The upper and lower concentration levels of each carbon number present in the substance composition shall be specified in the "Brief description" field in IUCLID section 1.2. Details of the protocol followed to determine the concentration values of each carbon number shall be indicated in the same IUCLID field.

Where the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade.
This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 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), available on the ECHA website.

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

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).

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

The analytical data in section 1.4 should confirm the composition presented in section 1.2. The Registrant is accordingly required 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 should be attached in IUCLID section 1.4.

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]
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Director of Regulatory Affairs