

Decision number: CCH-D-0000002867-62-05/F

Helsinki, 19 September 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List no. 919-164-8), 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 concerning the registration dossier for Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List no. 919-164-8) submitted by [REDACTED] (Registrant), for the tonnage band of 1000 tonnes or more per year.

This compliance check resulted in a decision adopted by ECHA in accordance with Article 41(1) of the REACH Regulation (1 August 2011, CCH-D-0000001637-70-03/F). Pursuant to Articles 42(1) of the REACH Regulation, ECHA has examined the information submitted in consequence of that decision and considers that the present decision is necessary.

The present decision is based on the registration dossier as submitted with submission number [REDACTED]. This decision does not take into account any updates after 12 June 2014, 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.

On 26 September 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.

On 26 October 2012 the Registrant provided comments on the draft decision to ECHA describing their position but with a commitment to update the dossier within 6 months of receipt of the Draft Decision addressing the issues raised in the Draft Decision.

Subsequently there was a change in the Lead Registrant for this joint submission. On 08 November 2013 ECHA sent a communication regarding pending obligations following transfer of Lead Registrant role and to which there has been no response. In the meantime there has been no update of the dossier.

On 12 June 2014 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.

This compliance check concerns standard information requirements relating only to substance identity (Annex VI section 2 of the REACH Regulation). The initial compliance check decision and the present one do not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

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.1.a) below;
- b) The composition (Annex VI, 2.3), as specified under section III.1.b) below;
- c) Spectral data (Annex VI, 2.3.5.), as specified under section III.1.c) below;
- d) The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as specified under section III.1.d) below.

Taking into consideration the data currently available in the dossier, 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 **2 January 2015**.

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. In accordance with Article 10(a)(ii) of the REACH Regulation, any registration dossier shall contain this information.

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 UVCB. Information required to be provided according to Annex VI section 2.1 of the REACH Regulation on the naming of UVCB substances shall consist of two parts: (i) the chemical name and (ii) a more detailed description of the manufacturing process, as described 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" thereafter.

ECHA observes that the Registrant did not provide sufficient information on the naming of the registered substance (as explained under points (i) and (ii) thereafter).

(i) Information on the chemical name to be submitted by the Registrant

- A chemical name representative for the registered substance must be submitted

The chemical name ("Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)") included in section 1.1 of the updated dossier indicates that the registered substance is composed mainly of n-alkanes, isoalkanes, cyclic alkanes and aromatics within the carbon number range of C10-C13. However the compositional information provided in section 1.2 and the analytical results attached in section 1.4 ("C10C13 NIC_HAR ECHA_compliance check.pdf") of the updated dossier indicates that the registered substance does not contain any n-alkanes. Therefore ECHA concludes that the provided name is not representative for the registered substance and needs to be revised.

Accordingly, the Registrant is required to provide the chemical name which is representative for the registered UVCB substance.

(ii) A detailed manufacturing process description to be submitted by the Registrant

Based on the information provided by the Registrant regarding the composition of the registered substance, ECHA concludes that the exact identity and concentration levels of the individual constituents within the hydrocarbon classes reported in section 1.2 of the updated dossier are not sufficiently known for the UVCB substance to be identified by its composition alone. ECHA also underlines that the chemical name used by the Registrant to identify the registered substance, which is based on its composition, does not allow for an accurate and complete identification of the substance. 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.

- The identity of the source used (in terms of identity and upper and lower concentration levels of each individual constituent) must be submitted

The Registrant identified the source used for the manufacturing of the registered substance as "kerosine". The identity of the exact source has not been identified to a sufficient level of detail as the description does not include any information on the exact identity and predominance of the individual hydrocarbon classes and carbon numbers which the source consists of. ECHA considers that the composition of a substance generically described as "kerosine" 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 and upper and lower concentration levels of each hydrocarbon class and the carbon number range associated to each hydrocarbon class) 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 and upper and lower concentration level of each hydrocarbon class (specifying also the carbon number range associated to it) present in the composition of the source. The Registrant shall ensure that the specific source generically designated as "kerosine" in the updated dossier is designated 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.

- The description of the manufacturing processing steps must be submitted by the registrant

The Registrant indicated that the registered substance is the result of the hydrotreatment of kerosine followed by distillation. 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 the hydrotreatment step, including the parameters used. The information shall be supplemented with details of the reaction mechanisms involved. For instance, where the hydrotreatment 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;
- Description of any other reaction(s) that do not involve hydrotreatment
- 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 hydrocarbon classes reported in the composition 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 corner stone 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.

Furthermore the Registrant indicated overly broad concentration ranges of ■ % - ■ % for the constituents "C10-C13 isoalkanes", "C10-C13 cycloalkanes" and "C10-C13 aromatics" in IUCLID section 1.2, which is not justified by the manufacturing process description due to its lack of detail (see p III a). The information on the concentration ranges (minimum and maximum) for each carbon number (i.e. C10, C11, C12, and C13), which is important in order to understand the variability of the composition of the registered substance, have also not been provided.

Therefore the Registrant is requested to amend the concentration range values for the different hydrocarbon groups.

In addition, for each detected carbon number an overall concentration range (minimum and maximum value) must be specified independent of each hydrocarbon class which means without differentiation between e.g. n-alkanes, isoalkanes, cyclics and aromatics.

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: Details of the protocol followed to determine the different concentration values of each hydrocarbon class 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&A8 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) Spectral data (Annex VI, 2.3.5.)

ECHA observes that the Registrant has not provided a nuclear magnetic resonance (NMR) spectrum or mass spectrum (MS). An infra-red (IR) spectrum was also missing from the updated dossier. In the previous decision dated 1 August 2011 ECHA requested the Registrant to provide an IR spectrum and NMR spectrum (or as an alternative to an NMR spectrum a mass spectral analysis). The Registrant decided to provide mass spectral analyses. However the method followed for the mass spectral analysis is not appropriate for the registered substance (see III d) point 1 below). In addition, the registrant did not include any mass spectrum as part of this analysis. The IR spectrum was also absent from the updated dossier. ECHA points out that the inclusion of spectra is a formal information requirement under Annex VI section 2.3.5. Spectral data is essential for ECHA to verify and have a representation of structural and compositional information on the registered substance.

In addition the justification for not providing a NMR spectrum given in the analytical methods and spectral data field in section 1.4 of the updated dossier is not acceptable as an NMR spectrum of the substance can provide qualitative information on the presence/absence of certain hydrocarbon classes and specific constituents as well as give an indicative relative molar ratio in the substance. In addition the Distortionless Enhancement by Polarization Transfer (DEPT) technique can be used for determining the number of protons directly attached to individual carbon-13 nucleus thus providing an indication of linearity or branching of the carbon chain.

Taking into account the number of constituents the registered substance consists of, ECHA considers that nuclear magnetic resonance spectroscopy will provide more appropriate analytical data to fulfil this specific information requirement as opposed to mass spectroscopy. Therefore, the Registrant is required to provide ¹H-NMR, ¹³C-NMR, DEPT 45, DEPT 90 and DEPT 135 spectra. The Registrant is also required to provide the missing IR spectrum.

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

- d) The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

ECHA observes that a part of the analytical methods used for the identification of the substance is not appropriate for the registered substance and that the description of the analytical method does not contain sufficient details to identify the registered substance, including its composition, as required by Annex VI, Section 2.3.7 of the REACH Regulation.

More specifically ECHA notes the following incompliances:

- o Determination of PINA for each carbon number
An analytical method for the separation of the hydrocarbons by carbon numbers and hydrocarbon classes (the PINA split by carbon number) has been provided. However it is not clear how the branched and cyclic alkanes have been distinguished using this method.

The Registrant is accordingly required to select valid methods for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance and to provide the description of these analytical methods. 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. If the description is not sufficient for the method to be reproduced by any third party laboratory, ECHA will consider the description insufficiently detailed. In that case, the information requirement under Annex VI section 2.3.7 will not be fulfilled.

According to the information provided in section 1.4 of the updated dossier, the overall content of aromatic constituents was determined by UV spectroscopy. The Registrant has specified that the content of aromatic constituents is analyzed to be ██████% but full details of any calculations necessary to establish the analysed concentration of the aromatic fraction is not provided. This information is required to be submitted.

As for the reporting of the data in the registration dossier, the information should 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.

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/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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