ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002873-69-04/F Helsinki, 18 April 2013

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

For Paraffins (petroleum), normal C>10, CAS No 64771-71-7 (EC No 265-232-9), 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 Paraffins (petroleum), normal C>10, CAS No 64771-71-7 (EC No 265-232-9) 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 18 January 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 concerns standard information requirements relating only to substance identity (Annex VI section 2 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 3 September 2012.

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.

By 26 October 2012 the Registrant did not provide any comments on the draft decision to ECHA. The deadline to provide requested information was changed from 2 months to 3 months to make it in line with the time given to lodge a potential appeal.

On 18 January 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.1.a) below;
b) The composition (Annex VI, 2.3), as specified under section III.1.b) below;
c) 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 **18 July 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. 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 a multi constituent substance. However based on the provided EC name (Paraffins (petroleum), normal C>10) ECHA concludes that the registered substance is a Substance 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" thereinafter.

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

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

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

  The Registrant did not provide any chemical name required to be provided in the "IUPAC name" field, as indicated in chapter 8.2.4 of the Guidance. The EC name alone is not sufficiently representative of the registered substance as it only describes in generic terms its composition (i.e. normal paraffins C>10) without defining the actual normal-paraffin fraction covered.

  Accordingly, the Registrant is required to provide the chemical name in the "IUPAC name" field which is representative for the registered UVCB substance. The chemical name shall define unambiguously the normal paraffin fraction actually covered by the registration.

(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 registration dossier are not sufficiently known for the UVCB substance to be identified by its composition alone.

The EINECS description is given as follows: "A combination of normal paraffins having carbon numbers predominantly greater than C10 obtained by urea adduction or molecular sieve processes." However the information on the manufacturing process given in section 3.1 of the registration dossier does not indicate that "urea adduction" or "molecular sieve processes" are part of the manufacturing process.

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 [redacted]. The identity of the exact source has not been identified as the provided information does not include any chemical name, description and other identifier (such as EC and CAS number) for the source. In addition, the description does not include any information on the exact identity and predominance of the individual constituents and groups of constituents which the source consists of. Compositional information of that source (in terms of identity and upper and lower concentration levels of each individual constituent) is necessary for the identification of the registered substance.

The Registrant is accordingly required to specify the chemical name, description and other identifiers (such as EC and CAS number) for the source, the identity and upper and lower concentration level of each constituent and group of constituents present in its composition. 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 "[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:

- [redacted] affects the composition of the registered substance must be also included;
- Description of any other reaction(s) that do not involve [redacted];
- Description of the step used to [redacted];
- Other relevant process steps and parameters

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 or different processing steps, 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.

More specifically, ECHA notes that the Registrant has only provided the typical concentration range of [redacted] for all constituents specified in section 1.2 of the IUCLID dossier. The information on the concentration ranges (minimum and maximum) for each constituent that is important in order to understand the variability of the composition of the registered substance, have also not been provided.

Therefore the Registrant is required to specify a concentration range (minimum and maximum value) for each detected individual constituent.

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 individual constituent was obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). For this purpose, the Registrant shall demonstrate that each minimal and maximal concentration value to be reported in the composition does not constitute an underestimation or overestimation of the actual value for that substance. 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 individual constituent shall be provided in the Remarks field of the corresponding repeatable block for that individual constituent.

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) 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 incompliance:

The Registrant provided a description of a GC analytical method used for determining the carbon number distribution. According to this method, the normal paraffins have been used as a basis, with timed windows set up so intermediate peaks are assigned the carbon number of the nearest n-paraffin. The Registrant also described a method to quantify alkanes and mono- and di-or poly aromatic hydrocarbons. However, the method(s) used for the quantification of each individual alkane constituent and group of constituents required to be reported has not been described.

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.

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/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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