

Final decision: CCH-D-0000002342-84-03/F

Helsinki, 2 August 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Reaction product of Distillates (petroleum), acid-treated heavy naphthenic and calcium oxide (List No 930-592-4), 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 Reaction product of Distillates (petroleum), acid-treated heavy naphthenic and calcium oxide (List No 930-592-4) submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 14 June 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.

The compliance check was initiated on 30 January 2012.

On 10 February 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 9 March 2012 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received and did amend the draft decision.

On 14 June 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.

This compliance check decision does 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. (a) below;
- b. Composition of the substance (Annex VI, 2.3.), as specified under section III. (b) below;
- c. Spectral data (Annex VI, 2.3.5.): an ultra-violet (UV) spectrum and an infra-red (IR) spectrum as specified under section III. (c) below;

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 October 2012**.

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 Articles 10 and with Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

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, 2.1.)

Annex VI section 2.1. of the REACH Regulation requires the Registrant to provide the Name or other identifier of the registered substance. ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH¹ the naming of UVCB substances shall consist of two parts: the chemical name and a more detailed description of the manufacturing process. ECHA observes that the Registrant did not provide appropriate information for the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

¹ <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach>

More specifically, the Registrant provided a chemical name indicating that the registered substance corresponds to the reaction products of the very specific petroleum raffinate "Distillates (petroleum), acid-treated heavy naphthenic" with calcium oxide. However, ECHA observes that the process circumstances under which the substance is manufactured from the petroleum raffinate are ambiguous. According to the technological process description given in IUCLID section 3.1, the petroleum raffinate to which calcium oxide is contacted should be part of sludge in a lagoon. The presence of such a raffinate in the environment can not be understood. Furthermore, the process used for the isolation of the registered substance is unclear as the Registrant only specifies that the substance is "hung on a designated place".

Accordingly, the Registrant is requested to provide a description of the process used for the manufacturing of the registered substance. The description shall include the identity of the starting materials used, the ratio of the starting materials and details of the most relevant steps taken during processing, including a description of the reaction types taking place and the corresponding process parameters used during the synthesis of the registered substance and the process circumstances used for its isolation. The Registrant shall also ensure that the chemical name assigned to the registered substance is consistent with the description of the manufacturing process and representative of the registered substance. The Registrant is therefore requested to revise the provided chemical name accordingly.

As for the reporting of the chemical name and description of the manufacturing process of the UVCB substance in IUCLID, further technical information is available in paragraph 2.1 of the Data Submission Manual 18 on the ECHA website.²

On 10 February 2012 the Registrant was notified of the draft decision and was invited to comment within 30 days. In his comments submitted to ECHA on 9 March 2012 the Registrant has provided detailed information on the manufacturing process. However based on the provided description on the manufacturing process, ECHA notes that the provided substance name "Reaction product of Distillates (petroleum), acid-treated heavy naphthenic and calcium oxide" is not appropriate for the substance. The current chemical name of the source which is treated with CaO is not representative of the specific sludge used for the manufacturing of the registered substance. Therefore the chemical name specified in the "IUPAC name" field in section 1.1 of the IUCLID dossier shall be revised.

(b) Composition of the substance (Annex VI, 2.3.)

Annex VI, section 2.3. of the REACH Regulation requires the Registrant to provide the composition of the substance. 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 registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, the Registrant reported the organic constituents present in the composition of the substance under one generic entry and indicated that this organic fraction is a petroleum fraction containing saturated, unsaturated, aromatic and polyaromatic hydrocarbons. ECHA points out that the compositional information on these constituents is not sufficiently specific as it neither provides details on the chemical nature

² <http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration>

of the saturated, unsaturated and aromatic hydrocarbons present in the substance nor does it specify their respective concentrations.

In addition, ECHA notes that the Registrant reported the presence of different inorganic calcium salts under one generic entry and listed the main counter-anions. ECHA observes that the Registrant did not provide any information on the crystalline modification of each inorganic constituent and their respective concentrations.

Furthermore, ECHA notes that the Registrant did not specify any information on the concentration ranges of the reported constituent and groups of constituents. Without this information, the variation in the composition of the substance can not be established. In line with these observations, ECHA concludes that the composition provided by the registrant is not sufficiently detailed for ECHA to establish the composition of the registered substance.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH³, the Registrant should note that, for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of $\geq 10\%$ shall be identified and reported individually;

- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and

- Other constituents shall be identified as far as possible by a description of their chemical nature.

For the organic fraction, a subdivision of the constituents according to the hydrocarbon class to which they belong (linear/branched/cyclic alkanes, linear/branched/cyclic alkenes, mono-/di-/tri- aromatic hydrocarbons as a baseline) is necessary for this purpose. The carbon number range for each hydrocarbon class should be reported in the remarks field of each constituent block.

For the inorganic fraction, reporting of the crystalline constituents as such (i.e. as respective minerals) and the amorphous constituents as far as possible by generic descriptions of their chemical nature is appropriate.

The Registrant is accordingly requested to report the missing compositional information of the registered UVCB substance, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the composition 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 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 18 on the ECHA website.⁴

³ <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach>

⁴ <http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration>

The Registrant shall ensure that the water in the substance, which can be considered as a solvent, is excluded as far as possible from the composition to the extent it can be separated without affecting the stability of the registered substance.

ECHA highlights that the Registrant shall also ensure that the compositional information is verifiable and therefore supported by qualitative and quantitative analytical data, as required under Annex VI section 2.3.7. 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.

In his comments submitted to ECHA on 9 March 2012 the Registrant indicated to "complete the list of components with all determined substances in the updated dossier". From this statement it is not clear to ECHA whether the Registrant will also include groups of constituents in section 1.2 of the IUCLID dossier as indicated above and perform additional analyses to identify these groups of constituents.

ECHA understands, from the provided description of the manufacturing process, that the registered substance is complex and may have a composition presenting an especially high variability. However, to enable ECHA to have a precise chemical representation of what the substance consists of, ECHA maintains the request to report the groups of constituents as indicated above. In case of inhomogeneous distribution of the composition of the starting material in the lagoons, the registrant may provide a scientific justification as to why the typical concentration levels can not be determined. However the Registrant shall indicate the minimum and maximum concentration of each constituent and group of constituents required to be reported in the composition in order to represent the variability of the composition.

(c) Spectral data (Annex VI, 2.3.5.)

IR and UV spectra are standard information requirements of Annex VI section 2.3.5 of the REACH Regulation. ECHA notes that the registration does not contain appropriate UV and IR spectral data, as required under Annex VI section 2.3.5 of the REACH Regulation. ECHA regards this required information scientifically relevant for the registered substance, in particular its organic fraction, for the following reasons:

- The substance absorbs in the UV range due to the presence of chromophores in the composition. A UV spectrum representing the absorption of these constituents in the UV range can therefore be recorded;
- The IR spectrum displays characteristic vibration bands of covalent bonds in molecules present in the substance, including characteristic vibration bands from the hydrocarbon classes expected to be present.

Accordingly, the Registrant is requested to provide the missing UV and IR spectral data.

As for the reporting of the spectral data in the registration dossier, the information should be attached in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for the recording of the spectra is specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

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.

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