

Decision number: CCH-D-0000003911-76-04/F

Helsinki, 11 November 2013

**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 Crude sludge and Calcium oxide. Crude sludge is the mixture of by-products of petroleum hydrocarbons refining (especially Total petroleum hydrocarbons, Polycyclic aromatic hydrocarbons, acid-refined heavy petroleum distillates). The Crude sludge is neutralised by calcium oxide in the ratio 80:20. The maturing process proceeds under ambient conditions and takes for at least 3 days. Subsequently, the reaction product is processed mechanically., List No 930-592-4, submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 7.8. 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 1 August 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 17 September 2012.

On 12 December 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 10 January 2013 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 1 August 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) and (b), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit following information for the registered substance subject to the present decision:

- a calculated value for log P as well as details of the calculation method (Column 2 of Annex VII, 7.8.).

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 **12 May 2014**.

## 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. The scope of the present decision is the partition coefficient n-octanol/water (Section 7.8. of Annex VII of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1) of the REACH Regulation, any registration for a substance shall contain this information.

The technical dossier contains a sound justification why the test normally required by Annex VII, 7.8. cannot be performed. Column 2 however requires that in such cases the value for log P be calculated and that details of the calculation method be provided by the Registrant. The Registrant has not done so.

In his comments on the draft decision the Registrant indicated that calculation of the partition coefficient n-octanol/water is not possible as the substance is a UVCB, mostly inorganic in nature with some organic components. The Registrant also indicates that calculation of a log  $K_{ow}$  range for the organic part of the substance is not possible because the majority of the components are not identified and not quantified. ECHA does not consider this as a relevant justification for omitting information on partition coefficient n-octanol/water, in particular given the fact that the Registrant has provided partition coefficient information in the CSR for representative structures. This information should be included in section 4.7 of the IUCLID dossier and its origin and reliability fully detailed. ECHA concludes that neither in his registration nor in his comments on the draft decision has the registrant submitted a fully justified adaptation for the information requirement Annex VII, 7.8.

The Registrant is therefore requested to submit a calculated value for log P as well as details of the calculation method.

The Registrant is reminded that if he intends to fulfil this requirement by means of a qualitative or quantitative structure-activity relationship model ((Q)SAR), he will need to comply with Section 1.3. of Annex XI. Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, section R.6.1. (pages 9-66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

IV. Adequate identification of the composition of the modelled substance(s)

ECHA stresses that the information submitted by the Registrant and by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the substance(s) used for the new study must be suitable for use by all the joint registrants. Hence, the substance(s) should be appropriate to assess the properties of every substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate substance(s) modelled and to document the necessary information on their substance composition.

In addition, it is important to ensure that the substance(s) modelled in the new study is(are) appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the substance(s) used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the substance(s) tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. General requirements for the generation of information

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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](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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