EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114289146-42-01/F Helsinki, 21 November 2014

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

For Shale oils, CAS No 68308-34-9 (EC No 269-646-0), 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 for Shale oils, CAS No 68308-34-9 (EC No 269-646-0), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirement of Annex VII, Section 7.8 of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration 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 submitted after 4 September 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.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 28 March 2014.

On 11 July 2014 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 4 August 2014 ECHA received comments from the Registrant on the draft decision.

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

On 4 September 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.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision using an appropriate test method:

- partition coefficient n-octanol/water (Annex VII, 7.8.).

ECHA stresses that if the information on the partition coefficient n-octanol/water is provided as a defined range, the range has to be justified and remain within the applicability range of the applied test method. If HPLC test method (OECD Guideline 117, EU A.8) is used, then in accordance with the test method average retention data and interpolated Log Kow value(s) should be provided.

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 **28 May 2015**.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request in this decision, or to fulfil otherwise the information requirement with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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.

Instead of a value for the partition coefficient n-octanol/water an unbound range of >3.4 has been reported under the appropriate heading in the technical dossier. As no upper limit was indicated and there was not a distinct, well justified, value or range for risk assessment, the information provided does not determine the octanol/water partition coefficient. The Registrant is therefore requested to submit information on the value of the partition coefficient n-octanol/water using an appropriate test method on the registered substance.

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7(a), section R.7.1.8.3 (version 2.2., August 2013).
In his comments to the draft decision, the Registrant did not agree with the draft decision and argued that experimental studies cannot be performed according to the shake-flask method or the HPLC method. The Registrant stated that in the preliminary test, a low solubility in water was found by quantification by Total Organic Carbon (TOC). The Registrant also stated that the quantification of the test item by the TOC method in *n*-octanol is not suitable due to the interference of *n*-octanol. In addition, the Registrant stated that the registered substance is slightly surface active.

ECHA notes that the water solubility is reported in the technical dossier as 0.22 g/L as TOC, which falls within the range of moderately soluble substances. ECHA agrees that determination of TOC in *n*-octanol may be interfered by *n*-octanol and that the substance is considered slightly surface active. However, the current value (>3.4) reported by the Registrant is not sufficient for risk assessment purposes, especially when the Registrant has used log Kow value of 3.4 in estimating the bioaccumulation potential of the registered substance in the Chemical Safety Report (CSR), therefore probably underestimating the bioaccumulation potential of the registered substance. While it may not be possible to measure the log Kow using the recommended method for UVCB substances (HPLC method) due to surface active properties of the registered substance, it is required to report a representative value or a range of values for log Kow to be used in risk assessment.

Therefore, the Registrant shall provide information on log Kow that better describes the partition behaviour of the registered substance, and takes into account all constituents or groups of constituents reported for the registered substance.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and 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. The Registrant is reminded of his responsibility and that of the joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new study is 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 sample used for the new study must be suitable to assess these grades.
Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. 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://www.echa.europa.eu/regulations/appeals. 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 Evaluation