EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002759-61-02/F Helsinki, 19 November 2012

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

For Phenol, alkylation products with C10 - 15 branched olefins derived from propene oligomerization, calcium salts, sulfurized, carbonates, overbased, (EC No 272-234-3), 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 standard information requirements relating to substance identity (Annex VI, Section 2 of the REACH Regulation) of the registration dossier for Phenol, alkylation products with C10 - 15 branched olefins derived from propene oligomerization, calcium salts, sulfurized, carbonates, overbased, (EC No 272-234-3) 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 6 September 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.

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 19 April 2012.

On 31 May 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 June 2012 ECHA received comments from the Registrant on the draft decision. The Registrant indicated in his comments that he would address most of the information required by ECHA through an updated registration dossier.

On 28 June 2012 the Registrant updated his registration dossier. ECHA considered the Registrant's comments received as well as the updated registration dossier. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 6 September 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.

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 (Annex VI, 2.1 of the REACH Regulation), as specified under section III.(a) below;
b. Composition of the substance (Annex VI, 2.3.), as specified under section III.(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 of the REACH Regulation), as described 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 **19 February 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. The scope of the present decision covers information requirements relating to substance identity (Section 2 of Annex VI of the REACH Regulation). In accordance with Article 10(a)(ii) of the REACH Regulation, any registration made pursuant to Chapter 1 of Title II of the REACH Regulation shall contain this information.

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.)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). According to the ECHA "Guidance for the identification and naming of substances under REACH and CLP" (Version: 1.1, November 2011; referred to as "the Guidance" thereinafter), 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 sufficient and appropriate information for the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

ECHA notes that the Registrant modified the chemical name of the registered substance from "phenol, dodecyl, sulfurized, carbonates, calcium salts, overbased" used in the previous registration dossier (submission number [redacted]) to the following "phenol, alkylation products with C10 - 15 branched olefins derived from propene oligomerization, calcium salts, sulfurized, carbonates, overbased" used in the current registration update. ECHA acknowledges that the name provided in the updated dossier specifies that the registered substance is an alkylation product with C10-C15 branched olefins derived from propene oligomerisation. However, other information contained in the registration dossier were not reflected in the chemical name, as explained below.

More specifically, the Registrant reported, as part of the registration update submitted on 28 June 2012, the presence of the substance "[redacted]" added in order to allow the formation of a stable colloid and identified it as stabiliser for the registered substance. While the composition of the registered substance reported by the Registrant would indicate a significant contribution of [redacted] (up to [redacted] (w/w) according to the information in IUCLID section 1.2), the registrant did not reflect the presence of [redacted] in the assigned chemical name. The approach followed by the Registrant would be consistent with the naming conventions specified in chapter 4.3.1.1, with reference to chapter 4.2, of the Guidance as long as [redacted] could be defined as a stabiliser. ECHA however points out that, in line with to Article 3(1) of the REACH Regulation, a stabiliser is added in order to preserve the stability of a substance. The role of a stabiliser is therefore limited to preserving the chemical integrity of already formed constituents ending up in the composition of the manufactured substance. Substances added in order to allow the chemical formation and/or physical order of the constituents ending up in the manufactured substance shall not be regarded as stabilisers. It follows that the [redacted] shall not be regarded as a stabiliser. To the extent that the quantity of [redacted] reported in the composition is not a solvent which can be removed without affecting the stability of the substance or changing its composition, the constituents of [redacted] shall be regarded as constituents of the registered substance. As [redacted] contributes extensively to the composition, the chemical name shall refer to the presence of [redacted] to reflect as far as possible its actual identity.

In addition, ECHA notes that, in the reference substance dataset in IUCLID section 1.2, the registrant indicated that the group of constituents "phenol, alkylation products with C10 - 15 branched olefins derived from propene oligomerization" is expected to be around [redacted] substituted in the para- position. Since this group of constituents is the residual alkylphenol of the unreacted starting material, this implies that [redacted] of the starting material consists of constituents where the relative position of the alkyl substituent on the phenol ring is para-. The predominance of these constituents has however not been reflected in the chemical name used to designate the starting material as part of the chemical name of the registered UVCB substance.
ECHA therefore concludes that the chemical name assigned by the registrant is not sufficiently representative of the registered substance.

Elements of the manufacturing process description which are essential for the identification of the registered substance are also missing from the dossier. In particular, the Registrant did not specify the exact ratio of the different starting materials used for the manufacturing.

In line with the above, the Registrant is accordingly requested to specify a chemical name that is representative of the registered substance. The Registrant shall ensure that the chemical name reflects the exact identity of the alkylphenol and oil starting materials used.

Moreover, the Registrant shall provide the missing information on the manufacturing process description mentioned above (i.e. exact ratio of starting materials).

As for the reporting of the information in IULCID, the chemical name and the manufacturing process description shall be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively.

The Registrant shall ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

(b) Composition of the substance (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 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 as part of the registration update submitted on 28 June 2012, the Registrant identified the "[redacted]" as a stabiliser for the registered substance. As already explained in section III.(a) hereinabove, such substance can not be defined as preserving the stability of the registered substance. The constituents of [redacted] which end in the composition of the registered substance shall be regarded as constituents of that substance and reported as such in the composition.
In addition, the identity and concentration level (in terms of upper and lower concentration values) of the constituents originating from the [redacted] have not been specified to a sufficient level of detail. ECHA notes that the Registrant provided information on the content of [redacted] in saturated, aromatic and polar constituents. However, further information on the identity and concentration level of the different hydrocarbon classes within the reported groups of constituents is necessary for an unambiguous identification of [redacted].

According to chapter 4.3 of the Guidance, the Registrant should note that, for UVCB substances presenting a large number of constituents such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and the 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 generic description of their chemical nature. The identification of these unknown constituent must here again be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. For the hydrocarbon constituents originating from the "[redacted]", the reporting of the different hydrocarbon classes (including linear alkanes, branched alkanes, cycloalkanes, their unsaturated counterparts and the aromatic constituents presenting the same number of aromatic cycles in their structure (mono-aromatic, di-aromatic, ...) is necessary as a baseline for ECHA to establish the composition of the substance. For each group of constituents, quantitative information on the carbon number distribution shall also be specified to conclude on the compositional profile of the constituents within the group.

The Registrant is accordingly requested to complete and correct the abovementioned information on the composition of the registered substance and on the identity of the individual constituents and groups of constituents present, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the information in IUCLID, the following applies: 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 other 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. Information on the carbon number distribution within the relevant groups of constituents shall be specified in the Description field of the reference substance for that group.
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) on the ECHA website.

The Registrant shall ensure that the reported composition is verifiable and therefore supported by the description of the analytical methods used for the identification and quantification of the constituents required to be identified and quantified, in line with Annex VI section 2.3.7. The description shall be sufficient for the methods to be reproduced and therefore include details of the experimental protocols followed, any calculation made and the results obtained.

(c) The description of the analytical methods (Annex VI, 2.3.7.)

ECHA notes that the Registrant has not provided any description of the analytical method used for the quantification of the registered substance including its constituents as required by Annex VI, 2.3.7. of the REACH regulation.

ECHA notes that the Registrant has attached an HPLC analysis of the registered substance. However, this information is part only to a certain degree of a quantitative analysis of constituents and groups of constituents. Furthermore, the analytical information reported in the dossier does not provide any description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition, in line with the requirements specified in section III.(b) above. ECHA therefore concludes that the provided chromatographic analysis can not be used as such to draw any conclusion on the composition of the registered substance.

In the updated dossier, the Registrant has provided a justification attached in IUCLID section 1.4, explaining that the quantification of the constituents and groups of constituents is determined based on mass-balance calculations, some direct measurement and sensible assumptions based on likely stoichiometry. On this basis, the Registrant has calculated the percentage ranges for probable constituents of the registered UVCB substance. Moreover, the Registrant has indicated that extensive methodological work and multiple analyses were carried out in order to confirm the constituents listed in the compositional information in IUCLID section 1.2.
Nevertheless, the Registrant has not attached any of the above mentioned analyses and calculations. ECHA underlines that it is essential to verify the compositional information provided in IUCLID section 1.2 with analytical data and/or analyses conducted. The

Registrant should note that the justification alone is not sufficient to demonstrate how the compositional values were derived. Therefore the Registrant should document the analysis and calculations carried out to derive the quantification of the substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. 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. The information shall be sufficient for ECHA to verify both qualitatively and quantitatively the compositional information required to be specified in the dossier.

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

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]
Jukka MALM
Director of Regulatory Affairs