ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002457-71-03/F Helsinki, 27.08.2012

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

For Alcohols, lanolin CAS No 8027-33-6 (EC No 232-430-1), 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 Alcohols, lanolin CAS No 8027-33-6 (EC No 232-430-1), submitted by [redacted] (the 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 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 8 February 2012.

On 25 April 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 25 May 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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.), specifically description of the manufacturing process, as described under section III.(a) below;
b. Composition (Annex VI, 2.3.), as specified under section III.(b) below;
c. Spectral data (Annex VI, 2.3.5.), as specified under section III.(c) below;
d. Chromatogram (Annex VI, 2.3.6.) as specified under section III. (d) below;
e. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, Section 2.3.7.) as specified under section III. (e) 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 January 2013.**

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, 12 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.)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances such as the registered substance shall consist of two parts: the chemical name and a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH (Version: 1.1, November 2011). ECHA observes that the Registrant did not provide appropriate information on the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the registrant identified the registered UVCB substance using the EINECS entry for "Alcohols, lanolin". In line with the EINECS general description for this entry, the registered substance corresponds to the alcohol constituents collected from the hydrolysis of lanolin. ECHA however notes that the manufacturing process specified in IUCLID section 3.1 does not refer to the lanolin alcohols but to a substance including, in its composition, a subset of the alcohols collected from the saponification of lanolin. In particular, the described process involves the removal, whether partial or complete, of the "cholesterol" alcohol constituent derived from lanolin using chromatographic technique. ECHA points out that such physical derivation is a significant step in the process as it determines the composition of the substance resulting from this process. Additionally, the resulting composition does not correspond to the composition of lanolin alcohols as it involves the

selective removal of an alcohol derived from lanolin. Consequently, the result of such refinement is to be regarded as a different substance for which separate registration obligations apply under REACH.
ECHA therefore concludes that the description of the manufacturing process provided in the dossier does not refer to the registered substance "Alcohols, lanolin".

The Registrant is accordingly requested to revise the information on the description of the process used for the manufacturing of the UVCB substance corresponding to the EINECS entry for "Alcohols, lanolin" which is the subject of this registration. The information shall include details of the source and steps carried out for the synthesis and isolation of the substance. For each step, the relevant process parameters (such as identity and ratio of reactants, operating parameters (temperature and pressure), etc.) shall be specified. The Registrant shall ensure that the process description solely refers to the manufacturing of the EINECS-listed UVCB substance "Alcohols, lanolin". In particular, the Registrant shall remove from the description any information on the manufacturing of the substance resulting from the partial or complete removal of the "cholesterol" alcohol constituent from "Alcohols, lanolin".
As for the reporting of the description in IUCLID, the manufacturing process description shall be specified in the Description filed of the reference substance assigned in IUCLID section 1.1.

(b) 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 appropriate and 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, ECHA notes that the concentration range of the cholesterol constituent specified by the Registrant indicates that the dossier covers also compositions presenting especially low content in that constituent or no cholesterol at all. In line with the observations made by ECHA on the naming of the registered substance in section III.(a) above, ECHA concludes that the reported compositional information does not specifically correspond to the registered substance but covers also other substances.
In addition, ECHA observes that the chromatographic information attached to the dossier indicates the presence of two constituents, desmosterol and lathosterol, which have not been reported in the composition. It follows that the composition of the registered substance has not been reported to the required level of detail.
Furthermore, the Registrant reported the presence of unknown constituents identified as "Unidentified long chain and sterol alcohols". ECHA points out that the reporting of these constituents using such a generic entry is not sufficiently detailed as information on the chemical identity of the sterols (in terms of chemical functionalisation and carbon number distribution) and the other alcohols also covered by that entry (according to parameters including backbone type, chemical functionalisation and carbon number distribution) can not be derived.
In line with the above, ECHA concludes that the reported compositional information is inappropriate and not sufficiently detailed.

According to chapter 4.3 of the Guidance for identification and naming of substances under REACH (Version: 1.1, November 2011), 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 ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must 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 substance which is the subject of this registration, the reporting of the unknown alcohols according to the structural parameters specified hereinabove is necessary for this purpose.

For each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is accordingly requested to correct the composition specified in the dossier so that the information specifically correspond to the substance which is the subject of this registration. The Registrant shall also report the missing compositional information.

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 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.
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: 1.0, June 2010) on the ECHA website.

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

ECHA observes that the registration does not contain any of the spectral data required according to Annex VI Section 2.3.5. of the REACH Regulation to support the identity of the registered substance. ECHA points out that the of Ultra-Violet (UV), Infra-Red (IR) and Nuclear Magnetic Resonance (NMR) spectra are a formal information requirement under Annex VI section 2.3.5. ECHA regards this required information scientifically relevant for the registered substance 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 chemical functionalities expected to be present in the composition;

- NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflects the relative abundance of individual atoms.

The Registrant is therefore requested to submit a UV spectrum, an IR spectrum and an NMR spectrum, such as a ^{1}H-NMR or a ^{13}C-NMR. As an alternative to an NMR spectrum, mass spectra (MS) generated as part of mass spectroscopic analysis for the elucidation of the structure of the constituents in the substance can be provided.

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

The Registrant shall ensure that the description of the analytical methods used for the recording of the UV, IR an NMR spectra are specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

(d) Chromatogram (Annex VI, 2.3.6.)

ECHA notes that the copy of a gas chromatogram has been attached to the dossier. However, ECHA observes that the registrant did not provide any report from the chromatographic analysis. In particular, a peak table with the associated retention times and peak area has not been included. ECHA points out that this information is required since it constitutes a numerical representation of the chromatogram.

Accordingly, the Registrant is requested to provide the report from the gas chromatographic analysis of the registered substance.

As for the reporting in the registration dossier, the information should be included in IUCLID section 1.4.

(e) Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide any appropriate 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, as requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided a copy of a gas chromatogram and assigned a number of constituents to some of the peaks detected. ECHA also notes that the analysis has been carried out in the presence of an internal standard. However, the dossier does not include any information as to how some of the chromatographic peaks have been assigned to specific constituents. In addition, the chromatogram attached to the dossier is not part of any description of a method for the quantification of the constituents present in the composition.
ECHA therefore concludes that the description of the analytical methods used for the identification of the registered substance is missing from the dossier.

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.

As for the reporting of the 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.

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Geert Dancet
Executive Director