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EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002317-77-04/F Helsinki, 29 March 2012

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

For Lemon, Citrus limonum, ext., CAS 84929-31-7 (EC 284-515-8), 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 Lemon, Citrus limonum, ext., CAS 84929-31-7 (EC 284-515-8), submitted by [redacted] (Registrant), latest submission number [redacted], for 100-1000 tonnes per year.

The compliance check was initiated on 11 November 2011.

On 2 December 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 2 January 2012 the Registrant did not provide to ECHA comments on the draft decision.

On 20 January 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. 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.

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II. Information required

1) 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): Any information which is suitable and necessary to allow ECHA to establish and verify the name of the registered substance, including the description of the manufacturing process, as specified under section III.1.a) below;
   b. Composition of the substance (Annex VI, 2.3.): Any information which is suitable and necessary to allow ECHA to establish and verify the composition of the registered substance, including names and concentration ranges of constituents, as specified under section III.1.b) below;
   c. Spectral data (Annex VI, 2.3.5.): UV-VIS and IR spectra for the substance and mass spectra from the GC-MS determination for all identified constituents, as specified under section III.1.c) below;
   d. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as specified under section III.1.d) 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 29 May 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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and 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.

1. 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):

The substance is considered a UVCB substance from biological origin. In general a UVCB substance name consists of two parts, the chemical name which should be included in the IUPAC name field and the more detailed description of the manufacturing process which should be indicated in the description field.

The Registrant did not report any specific chemical name of the registered substance but assigned the EINECS entry for "Lemon, ext." (EC number 284-515-8;

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CAS number 84929-31-7). Such entry corresponds to a generic identifier covering several substances with different compositions and is therefore not considered appropriate to identify the registered substance. In addition, ECHA notes that the trade names provided in section 1.1 seems to cover different substances. For example, [redacted] are obtained by using different manufacturing processes and would therefore be considered as different UVCB substances.

Therefore, the Registrant shall report a chemical name that is representative of the specific substance covered by this registration. It seems that based on the provided name of the registered substance, the substance is obtained from the skin of Citrus limonum Burm.f. (Rutaceae) by extraction. If the registered substance is the result of further processing of the extract, the manufacturing process used has to be reflected in the chemical name.

The Registrant shall also remove the CAS number 84929-31-7 as it covers e.g. essential oils, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Citrus limon, Rutaceae, which are considered different substances, and assign any appropriate CAS information (if available) corresponding to the specific substance registered. The CAS entry with CAS number 84929-31-7 may be reported under the "Related CAS information" field of the reference substance in the technical dossier. In addition, the Registrant shall remove any reference to trade names which do not refer to the substance covered by this registration.

ECHA notes that there is no process description given in section 1.1 of the IUCLID dossier and the Technological Process as described in section 3.1 of the dossier seems to refer to the general process for obtaining essential oils by extraction, but also to processes for obtaining condensates or terpenes by distillation as well as residues by distillation. Depending on the process used different substances can be obtained. Therefore the substance identity as described is unclear.

The Registrant shall note that as soon as an extract is further processed, the substance is no longer identical with the original extract. As a consequence the substance may be named differently than the original extract and the process description will also differ from that of the original extract. As a consequence each substance needs to be registered separately.

The Registrant shall therefore clarify which process is applicable to his substance and provide a detailed description of the manufacturing process. The process description should include information such as the tissue or the part of the organism used for extraction of the substance (i.e. skin of the lemon), the extraction method, the solvent used for the extraction, the purification process (if appropriate) and other relevant conditions, e.g. temperature/temperature range. The process description should further contain any concentration and/or fractionation step (if applicable) together with the additional (further) processing parameters. The Registrant shall include the information in the "description" field of the reference substance in section 1.1 of the IUCLID dossier.

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b) Composition of the registered substance: names and concentration ranges of the constituents (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.

Some of the constituents provided in section 1.2 of the IUCLID dossier have broad concentration ranges, e.g.:

- Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (4R)- (CAS number 5989-27-5) with [redacted]%;
- Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene- (CAS Number 127-91-3) with [redacted]%;
- 1,4-Cyclohexadiene, 1-methyl-4-(1-methylethyl)- (CAS number 99-85-4) with [redacted]%

The Registrant indicated in section 1.4 of the IUCLID dossier: *"The composition provided in the lead dossier is a representative composition for Lemon, Citrus limonum, ext. and is established after combined industry efforts under guidance of the European Federation of Essential Oils (EFEO). Constituent concentrations may vary within the ranges as indicated."*

Furthermore, the identity of the first listed constituent in section 1.2 of the IUCLID dossier is unclear as the EC entry specifies the R-isomer whereas the IUPAC name specifies the racemate. If the given EC entry 227-813-5 is correct, the Registrant shall amend the IUPAC name to: **(4*R*)-1-methyl-4-(prop-1-en-2-yl)cyclohexene**. In addition, the identity of the second listed constituent in section 1.2 of the IUCLID dossier is also unclear. If the given EC entry 204-872-5 is correct, both CAS and IUPAC names need to be amended to Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene- and 6,6-dimethyl-2-methylidenebicyclo[3.1.1]heptane respectively.

Therefore, the Registrant shall clarify the identity of the first and second listed constituents and revise the respective fields in the reference substances of the dossier. Furthermore, the Registrant shall revise the concentration ranges of the constituents so that this information is representative of the specific substance manufactured and/or imported by the Registrant himself. The Registrant shall note that a constituent such as (4*R*)-1-methyl-4-(prop-1-en-2-yl)cyclohexene (CAS number 5989-27-5) present in a substance with [redacted]% would suggest a well-defined substance.

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

The Registrant provided a waiver for not submitting Ultraviolet-Visible (UV-VIS), Infrared (IR), Nuclear magnetic Resonance (NMR) spectra and Mass Spectroscopy (MS). Although ECHA agrees with the Registrant that a substance obtained from a natural source may be very complex, the registered substance is of organic nature and thus contains groups which are UV active and exhibit very characteristic vibrations in the infrared range. The Registrant indicated that the composition of the substance was identified by using GC-MS. However the mass spectra corresponding to analyzed peaks were omitted in the IUCLID dossier and therefore it is unclear how the constituents determined by GC were identified.

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Therefore, the Registrant shall provide UV-VIS and IR spectra for the substance and mass spectra from the GC-MS determination for all identified constituents. As for the reporting of the spectral data in the registration dossier, the spectra should be attached in IUCLID section 1.4.

d) Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

The registration dossier does not contain the description of the analytical methods used for the qualitative analysis of the substance.

Consequently, there is not sufficient information to identify the composition of the substance.

Therefore, in line with Annex VI, 2.3.7. of the REACH Regulation, the Registrant shall provide a description of the methods used for the qualitative analysis of the substance or the appropriate bibliographical references, to identify the registered substance, including its composition and results of the method used. The description shall be given in such detail that the methods can be reproduced and the information shall include a detailed experimental protocol followed, the calculation used and the results obtained.

Regarding how to report this information in the IUCLID, the following applies: The Registrant should attach information on the analytical methods or the appropriate bibliographical references used for the identification and quantification of the substance and its composition 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]

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Director of Regulatory Affairs