EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114299716-31-01/F Helsinki, 20 May 2015

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

For Orange, sweet, ext., CAS No 8028-48-6 (EC No 232-433-8), 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 for Orange, sweet, ext., CAS No 8028-48-6 (EC No 232-433-8), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1. and 4.2. of the REACH Regulation relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI) or those of Annexes VII to IX relating to aquatic toxicity.

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 5 March 2015, 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 17 May 2013.

On 20 August 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 19 September 2013 ECHA received comments from the Registrant. On 18 October 2013 the Registrant updated his registration dossier (submission number [redacted]).

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 5 March 2015 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)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Title I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- a fully justified hazard classification of the registered substance for aquatic toxicity based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and the resulting hazard statement(s) in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a) and 4.1.4), as specified in section III below, or

- the scientifically justified reasons why no such classification is given in the technical dossier.

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 **27 August 2015**.

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 limited to classification and labelling for aquatic toxicity (Annex VI, Sections 4.1 and 4.2. of the REACH Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the dossier:

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In addition, for each entry, reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

In the present case, ECHA notes the following:

In his comments to the draft decision submitted on the Registrant agrees that the hazard classification for the aquatic environment according to CLP Regulation was incomplete. However, the Registrant also states in the comments that further information has become available requiring an update of the registration dossier including the update of the classification.

The original technical dossier (submission number [redacted]) included an aquatic acute toxicity study indicating an L(E)C_{50} equal to or lower than 1 mg/l which is considered reliable by the Registrant (Klimisch score 1 or 2). However, the Registrant did not classify the substance as Aquatic Acute Hazard Category 1 and did not use the resulting hazard statement "H400: Very toxic to aquatic life", which would be in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. and 4.1.4 of the CLP Regulation). In the original dossier classification Aquatic Chronic Category 1 (M-factor 1, H410: Very toxic to aquatic life with long lasting effects) was included. However, in the updated dossier submitted on 18 October 2013 (submission number [redacted]) this was changed to Aquatic Chronic Category 2 (H411: Toxic to aquatic life with long lasting effects). Furthermore, in the updated dossier the Registrant has refined the acute effect values.

In his comments to the draft decision the Registrant points out that the registered substance, orange citrus sinensis ext., is a UVCB substance of biological origin with Limonene, D- (EC No 227-813-5) being the main constituent (typical conc [redacted]%, range [redacted]%). The Registrant considers the limonene D- as the major constituent of the registered UVCB substance and the environmental risk characterisation is based on the PNEC derived for limonene D-. All acute aquatic toxicity tests selected as key studies have been performed with the registered UVCB substance using Water-Accommodated Fractions (WAFs). Based on this the Registrant has in his updated dossier revised the acute effect values to be based on loading rates instead of the limonene concentrations that were used in the original dossier. Based on the revised effect values, the Registrant has considered classification as Aquatic chronic category 2 to be sufficient for the registered substance.

ECHA notes that according to OECD guidance for testing on difficult substances (OECD 2000) the toxicity of complex multi-component substances, which are only partially soluble in water, can be determined by preparing water-accommodated fractions (WAFs) of them. According to the Guidance on the application of the CLP criteria (version 4.0, Nov 2013) the loading levels (EL50) from the WAF tests may be used directly in the classification criteria. However, ECHA notes further that the main constituent of the registered substance, limonene, D- (EC No 227-813-5), has a harmonised classification in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) as Aquatic Acute Hazard Category 1 and Aquatic Chronic Hazard Category 1. According to Article 11 of the CLP Regulation "*Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cut-off value in accordance with paragraph 3*". ECHA notes that as the concentration of this main constituent in the registered UVCB substance is up to [redacted]%, the harmonised classification of the main constituent should be taken into account in the classification of the registered substance.

ECHA notes that the technical dossier does not contain (scientifically justified) reasons relating to why the harmonised classification of the main constituent is not considered.

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP Regulation (taking into account the harmonised classification of the main constituent Limonene, D- (EC No 227-813-5)) and is consistent with the data on aquatic toxicity available in the registration dossier. The Registrant shall also provide resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (a) and 4.1.4) and a justification for the hazard classification used. In the alternative, the

Registrant is required to provide reasons why no such classification is given.

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

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]
Guilhem de Seze
Head of Unit, Evaluation