EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004883-66-04/F Helsinki, 22 August 2014

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

For ethyl (S)-2-hydroxypropionate, CAS No 687-47-8 (EC No 211-694-1), 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 for ethyl (S)-2-hydroxypropionate, CAS No 687-47-8 (EC No 211-694-1), submitted by [redacted] (Registrant).

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 6 March 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 17 July 2013.

On 20 November 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 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision. The Registrant acknowledged the information gaps identified by ECHA in section II.A. of that decision. Regarding the information related to the chemical safety assessment and the chemical safety report required in section II.B., the Registrant agreed to update the chemical safety report accordingly.

On 7 February 2014 the Registrant updated his registration dossier with the 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 6 March 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annexes VII, VIII and IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Vapour pressure (Annex VII, 7.5.; test method: EU A.4./OECD 104);
2. Activated sludge respiration inhibition testing (Annex VIII, 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD 209).

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Predicted no effects levels (PNEC) for freshwater, marine water, intermittent releases, sediment, soil and STP microorganisms (Annex I, section 3.3.1.), as specified under section III.B.1.;
2. A revised exposure assessment and risk characterisation for workers and consumers (Annex I, sections 5 and 6), as specified under section III.B.2.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **2 March 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 requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Vapour pressure (Annex VII, 7.5.)

"Vapour pressure" is a standard information requirement as laid down in Annex VII, Section 7.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Pursuant to Article 10 (a)(vi) this information should be provided in the form of a study summary.

The Registrant has however provided only a value as the only information for this standard information requirement, which according to the information provided by the Registrant stems from a publication. No information is provided how this value is measured. Accordingly, the information was not provided in accordance with the requirements of Article 10(a)(vi).

Pursuant to Annex XI, section 1.1.1. of REACH it is possible to adapt the standard information requirement using existing data if (1) the information is adequate for the purpose of classification and labelling and/ or risk assessment, (2) sufficient documentation is provided to assess the adequacy of the study; and (3) the data are valid for the end-point being investigated and the study is performed using an acceptable level of quality assurance.

As the Registrant only provided a value to meet this information requirement none of the conditions for adapting the standard information requirement in accordance with Section Annex XI, Section 1.1.1 have been met.

Pursuant to Annex XI, section 1.2. of REACH it is possible to adapt a standard information requirement on the basis of weight of evidence. However, if the Registrant sought to build a weight of evidence adaptation of the standard information requirement, he would have had to provide several independent sources of information. In the present case the Registrant has provided information from only one source of information.

Accordingly, as explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Vapour pressure (test method: EU A.4./OECD 104).

In his comments, the Registrant indicated his intention to perform the test requested.

2. Activated sludge respiration inhibition testing (Annex VIII, 9.1.4.)

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has waived testing on aquatic microorganisms using the following justification: "Ethyl lactate is readily biodegradable even at high concentrations. No toxicity was seen in biodegradation tests. No toxicity to micro-organisms is expected".

ECHA notes that the Registrant's claims are not supported by the actual data provided by the Registrant. The highest concentration tested by the Registrant in the biodegradation tests is 4 mg/L, which is a relatively low concentration for a biodegradation test. Thus, the registration dossier does not contain data to definitely conclude that microorganisms are not affected by the substance at concentrations higher than 4 mg/L.

Therefore, the justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annex VIII, section 9.1.4., or the general adaptation rules of Annex XI. Therefore, the adaptation proposed by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: EU C.11./OECD 209).

In his comments, the Registrant indicated his intention to perform the test requested.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Predicted no effects levels (PNEC) for freshwater, marine water, intermittent releases, sediment, soil and STP microorganisms (Annex I, section 3.3.1.)

Annex I section 3.3.1. of the REACH Regulation requires the Registrant to establish a PNEC for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

The ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.10 provides further details and specifically provides default factors which should be applied to derive PNECs.

Further, pursuant to Annex I section 3.3.2. if it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

The Registrant has not established the PNECs for freshwater, marine water, intermittent releases, sediment, soil and STP microorganisms arguing that no PNECs are needed since no adverse effects have been observed at the highest recommended concentration for aquatic tests on pelagic organisms..

ECHA would like to point out that according to Annex I, Section 3.3.1. the "*PNEC for each environmental sphere shall be established*" and according to Annex I, section 3.3.2. "*if it is not possible to derive the PNEC, then this shall be clearly stated and fully justified*". In this case, PNECs can be derived and the fact that no adverse effects have been observed at the highest recommended concentration for aquatic tests on pelagic organisms is not a reason to not do it. Therefore, the Registrant should derive the PNECs.

As explained above, the information provided on PNEC for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 3.3.1. Consequently it is necessary to derive the PNECs.

Therefore, pursuant to Article 41(1)(c) and (3) of the REACH Regulation, the Registrant is requested to submit PNECs for freshwater, marine water, intermittent releases, microorganisms in sewage treatment plants, sediment and soil using the assessment factors recommended by ECHA and re-assessment of related risks. The chemical safety report shall be amended accordingly.

2. A revised exposure assessment and risk characterisation for workers and consumers (Annex I, sections 5 and 6)

Annex I, section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Further, Annex I, section 6.5. of the REACH Regulation states that "for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out".

The Registrant has stated that "there is no indication of clear systemic effects" and therefore, no DNELs have been derived because no hazard has been identified. The registered substance is irritant (Eye Damage 1 and STOT Single Exp. 3 (respiratory irritation)) and the Registrant provided a qualitative assessment for the local effects accordingly. The Registrant states that "*the substance is classified for serious eye damage and respiratory irritation. A qualitative risk characterisation is needed for these health hazards. Implementation of the following RMMs, as appropriate, will ensure that the likelihood of an event occurring due to the irritating properties is negligible and the risk is considered to be controlled to a level of no concern. Normally only necessary when the mixture is classified for respiratory and/or eye irritation due to its ethyl lactate content (>= 1.0 % w/w): Respiratory protection: In case of insufficient ventilation wear suitable*

respiratory equipment. Breathing apparatus with filter (DIN 141). Hand protection: Solvent-resistant gloves (PVA/H4). Break through time > 8 hours. Eye protection: Tightly fitting safety goggles. Skin and body protection: Lightweight protective clothing".

ECHA notes, however, that the Registrant has provided information in support of a qualitative assessment that is not specific enough and without sufficient detail. The Registrant has used arguments like "*implementation of the following RMMs, as appropriate,...*" (not defined when appropriate) or "*in case of insufficient ventilation wear suitable respiratory equipment*" (not defined when ventilation is regarded as insufficient). It does not allow specific workplaces and downstream users either to recognise the conditions that lead to a requirement for application of the risk management measures or to identify the specific measures they have to implement for the different conditions identified for the safe use of the substance, and thus, the qualitative assessment provided is not adequate.

Therefore, pursuant to Article 41(1)(c) and (3) of the REACH Regulation, the Registrant is requested to provide a revised exposure assessment and risk characterisation for all the identified uses and detailing the operational conditions and risk management measures. The chemical safety report shall be amended accordingly.

Guidance on how to undertake a qualitative human health assessment is available in ECHA's Guidance on information requirements and chemical safety assessment (Version of November 2012), Chapter E.3, section E.3.4., pages 18 to 32, and in ECHA's Practical Guide 15: "How to undertake a qualitative human health assessment and document it in a chemical safety report".

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by 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

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 studies 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 studies 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://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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