EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004821-76-02/F Helsinki, 30 June 2014

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

For Yeast extract, Saccharomyces cerevisiae, CAS No 84604-16-0 (EC No 283-294-5), 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 Yeast extract, Saccharomyces cerevisiae, CAS No 84604-16-0 (EC No 283-294-5), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 9.2.1.1. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

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 28 August 2013.

On 10 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

By 24 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

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.

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), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex VII 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:

Ready biodegradability (Annex VII, 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD 310).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: MITI test (I), OECD 301C).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Closed bottle test, OECD 301D).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Manometric respirometry test, OECD 301F).

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 **7 January 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. The scope of the present decision covers endpoints relating to ready biodegradability (Annex VII, 9.2.1.1. of the REACH Regulation).

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, the endpoint 'ready biodegradability' (Annex VII, 9.2.1.1.) is a standard information requirement for registration for a substance produced or imported in quantities of one tonne or more per year.

According to column 1 of Section 9.2.1.1. of Annex VII of the REACH Regulation, a ready biodegradability study is required to fulfil the standard information requirements. Column 2 of Section 9.2.1.1. of Annex VII of the REACH Regulation further states that the study does not need to be conducted if the substance is inorganic.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

In the present case, the technical dossier contains ready biodegradability test conducted according to OECD test guideline 301 B "Ready Biodegradability: CO2 Evolution Test" as a key study. Biodegradation of 87-88 % was determined after 28 days and the Registrant concludes that the substance meets the criteria for ready biodegradability. Vapour pressure of 510 Pa is reported in the technical dossier Section 4.6.

The information provided in the registration dossier is not appropriate to conclude that the registered substance is readily biodegradable. Vapour pressure of 510 Pa reported in the technical dossier indicates high volatility of the registered substance. The OECD 301 B "Ready Biodegradability: CO2 Evolution Test" is not a suitable method for testing and

making conclusions on the ready biodegradability of volatile substances as such substances are not within the applicability domain of this test. Furthermore, in IUCLID section 5.2.1 (details on study design) the Registrant has indicated that the test has been performed in an open system and there are no details on how the high volatility of the substance may have potentially been taken into account in ready biodegradablity testing.

ECHA therefore considers that the information provided on this endpoint is not adequate to conclude on ready biodegradability. The technical dossier does not either contain acceptable adaptations in accordance with Column 2 of Section 9.2.1.1. of Annex VII or Annex XI for this standard information requirement.

Regarding the test method, depending on the substance profile, the Registrant may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA Guidance on information requirements and chemical safety assessment, Volume 5 Chapter R7b (November 2012) and in the paragraph below. The test guidelines include the description of their applicability domain.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to perform one of the following tests with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD 310).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: MITI test (I), OECD 301C).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Closed bottle test, OECD 301D).
or
Ready biodegradability (Annex VII, 9.2.1.1.; test method: Manometric respirometry test, OECD 301F).

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and 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. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study 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 study 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 study 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 study 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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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