EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005192-80-02/F Helsinki, 30 September 2014

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

For benzotriazole, CAS No 95-14-7 (EC No 202-394-1), 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 benzotriazole, CAS No 95-14-7 (EC No 202-394-1), submitted by [redacted] (Registrant).

The scope of this decision is limited to the standard information requirements of Annex I , Sections 0.1, 5.2.4 and 6.2 to 6.4, Annex VIII, Section 9.1.4 and Annex IX, 8.6.2. of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates submitted after 12 June 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.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2016.

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 2 December 2013.

On 16 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. That draft decision was based on submission number [redacted]

On 29 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision for the request of Activated sludge respiration inhibition testing and comments for the two other information requests.

On 5 March 2014 the Registrant updated his registration dossier with the submission number [redacted]

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

On 12 June 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

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)(d), 13 and Annex VIII of the REACH Regulation the Registrant shall submit the following information, where testing is required using the indicated test method and the registered substance subject to the present decision:

1. Activated sludge respiration inhibition testing (Annex VIII, 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD 209).

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 **6 April 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)(d) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

1. Activated sludge respiration inhibition testing (Annex VIII, 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD 209)

"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.

In the technical dossier the Registrant has provided as the key study a Test for Inhibition of Oxygen Consumption by Activated Sludge (ISO 8192). In the endpoint summary (Technical dossier, Section 6.1.7) the results of a Microtox test system (Vibrio fischeri) are provided.

ECHA notes that the Registrant justifies the given reliability score of 2 for the Test for Inhibition of Oxygen Consumption by Activated Sludge (ISO 8192) study with the following statement: "*according to national guideline, reliabilty restricted by missing information on exposure duration. Due to missing effect concentration of the control with the reference substance the study could not be validated. However, as further information on toxicity to STP microorganisms exposed to Tolyltriazole has been available and has shown effect concentrations in the same range the results from this study are considered reliable with restrictions.*"

ECHA notes that the Registrant does not provide all characteristics of the study, which are needed to provide sufficient information for an independent assessment of the study. The *ECHA Practical Guide 3 How to report robust study summaries* (Version 2.0, November 2012), Chapter 4.2.1., gives detailed explanation of which study characteristics should be reported for studies on Toxicity to micro-organisms. In detail, the test duration / total exposure duration and crucial details of the test design, such as the effect concentration of the positive control and test temperatare, are missing in the provided study summary. Based on that, ECHA considers the provided key study as not reliable.

In the endpoint summary of the technical dossier (Section 6.1.7), the Registrant makes a reference to the results of a microorganism toxicity study by Gruden et al., 2001 using Tolytriazole, regarded as an analogue substance. However, no justification is provided for this read-across and the Registrant does not provide a robust study summary for the study, which prevents an independent assessment of this information.

Further, the Registrant provided the information on the Microtox test system (Vibrio fischeri) in the endpoint summary of the technical dossier (Section 6.1.7) and not in the form of robust study summaries. This prevents an independent assessment of the information. Additionally, according to the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2, November 2012), Chapter R.7b, Section R.7.8.17.1., the Microtox test system (Vibrio fischeri) "*should be considered of low relevance for STPs*". Based on that, ECHA considers the provided study as not reliable.

In addition, the Registrant identifies "Use of Dishwash products" for the registered substance in Section 3.5 of the registration dossier. Therefore, widespread exposure, including direct exposure of STP microorganisms in sewage treatment plants receiving domestic wastewater, is anticipated.

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.

As described in ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2, November 2012), Chapter R. 7b, Section R.7.8.15., the preferred study for the generation of new data is an activated sludge respiration test.

In their comments on the draft decision, the Registrant agreed with the request to submit new information according OECD test guideline 209.

Therefore, pursuant to Article 41(1)(a) 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), OECD 209).

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

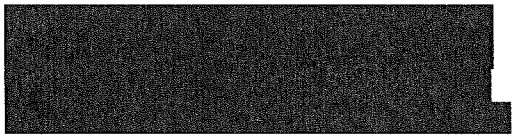
In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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