

Decision number: TPE-D-0000002363-80-03/F

Helsinki, 28.08.2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate, CAS No 15546-11-9 (EC No 239-594-3), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof to fulfil the information requirements set out in Annex IX for methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate, CAS No 15546-11-9 (EC No 239-594-3), by [REDACTED] (Registrant).

- Testing proposal: Viscosity of Liquids (OECD 114).

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 10 to 100 tonnes or more per year. This decision does not take into account any updates after 14 June 2012, 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

On 22 November 2011, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal set out by the Registrant in the registration dossier for the substance mentioned above.

On 6 March 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 21 March 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and amended the draft decision in section III.

On 14 June 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 of the receipt of the notification.

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.

II. Testing required

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

Viscosity of liquids (Annex IX, 7.17, test method: OECD 114).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **28 February 2013** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require a registrant to carry out a proposed test. The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

The proposed test referred to in Section II above is part of the standard information requirements as laid down in Annex IX of the REACH Regulation. As the dossier does not contain any information on the viscosity of the substance there is a data gap for this endpoint which must be filled by data from a valid test.

Moreover, a member of the joint submission for which the Registrant acts as lead registrant registered at a tonnage band of 100-1000 tonnes per annum, i.e. a tonnage level where the data requirements of the proposed tests have to be met. As indicated by the testing proposed by the Registrant, there is a necessity to generate the proposed data in order to be compliant with the information requirements of the REACH Regulation at a tonnage band of 100-1000 tonnes per annum, at least for members to the joint submission. Therefore, the Registrant shall carry out the proposed tests on viscosity, Annex IX, 7.17, test method: OECD 114 (Viscosity of Liquids).

During the commenting period, the Registrant agreed that the study will be carried out and that the results will be submitted to ECHA in form of an updated registration dossier.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, however, that this information, or the information submitted by other Registrants of the same 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 proposed test, 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 the joint Registrants of the same substance to agree with the test proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint Registrant. Finally, the study must be shared by the joint Registrants concerned.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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.


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