

For final decision: TPE-D-0000002554-75-05/F

Helsinki, 14 November 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS No 115895-09-5 (EC No 404-740-9), registration number: [REDACTED]

Addressee: [REDACTED]
[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 registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for for ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate, CAS No 115895-09-5 (EC No 404-740-9), by [REDACTED] (Registrant).

- Sediment toxicity: (OECD Guideline 218), Sediment-Water Chironomid Toxicity Test Using Spiked Sediment

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 10-100 tonnes per year. This decision does not take into account any updates after 19 July 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 from initiating a compliance check on the present dossier at a later stage.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 08 February 2012.

On 06 June 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.

By 06 July 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 19 July 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 22 August 2012 ECHA notified the Registrant of the proposal 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 within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided to amend the draft decision.

On 3 September 2012 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 8 October 2012 in a written procedure launched on 26 September 2012 and ECHA took the decision pursuant to Article 51(6) 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:

Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218) with adaptation following OECD series number 23 guidance document on aquatic toxicity testing of difficult substances and mixtures;

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **14 April 2014** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

Long-term toxicity testing on sediment organisms

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

Long-term toxicity to sediment organisms is a standard information requirement as laid down in Annex X, section 9.5.1. of the REACH Regulation. Although the current registration dossier concerns a substance manufactured in quantities of 10-100 tonnes per year, the Registrant has indicated a need to generate this information as stated in the above section II and provided the following justification:

'No toxicity data evaluating the effect of ethyl 3,5-dichloro-4-hexadecyloxybenzoate (AF-366) on sediment organisms are available. According to the standard requirements set in Regulation (EC) No 1907/2006, Annexes VII and VIII, information concerning the effects of the substance on sediment organisms does not need to be presented at this tonnage band. Nevertheless, due to the characteristics of the substance, a testing proposal for this compartment according to OECD 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment has been developed, and further assessment of the effects of

AF-366 on sediment organisms will be performed once the results from the test become available.' Furthermore the Registrant also provided a justification for the adaptation of the test method using OECD guidance 23 : ' Due to the poorly soluble nature of the test substance, a generator column (as proposed in OECD Series on testing and assessment Number 23, Guidance document on aquatic toxicity testing of difficult substances and mixtures, 2000) or a circulating system where low concentrations of the substance are added over a long period of time (hours to days) (according to 'Guidance on information requirements and chemical safety assessment, Chapter R.7b: Endpoint specific guidance' (ECHA, 2008)) should be used for spiking the test solutions.'

ECHA has examined this testing proposal considering all the relevant information available in the technical dossier. Considering that the substance has a very low water solubility and a high adsorption potential to sediments, exposure to sediment cannot be excluded. Furthermore, no risk characterisation ratio can currently be calculated using the equilibrium partitioning method and toxicity tests on aquatic organisms as no EC 50 could be estimated during these tests. Considering that, according to Article 12 of the REACH Regulation, the information required in the Annexes are minimum information requirements, ECHA accepts the testing proposed by the Registrant using the adaptation method required to test this substance and grants the time required to proceed to the testing and its preliminary research of the adequate adaptation method.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study:

- Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218) with adaptation following OECD series number 23 guidance document on aquatic toxicity testing of difficult substances and mixtures using the registered substance.

IV. Adequate identification of the composition of the tested material

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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study to be assessed.

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

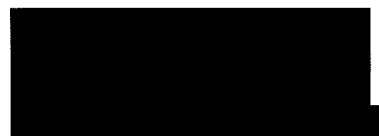
ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

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.



Geert Dancet
Executive Director