

Decision number: CCH-D-2114299680-38-01/F

Helsinki, 22 April 2015

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

For dibutyl terephthalate, CAS No 1962-75-0 (EC No 217-803-9), 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 dibutyl terephthalate, CAS No 1962-75-0 (EC No 217-803-9), submitted by [REDACTED] (Registrant). The scope of this compliance check decision is limited to the standard information requirement of Annex X, Section 9.5.1. 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 5 March 2015, 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 7 May 2014.

On 28 October 2014 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].

By 5 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 4 December 2014 and 14 January 2015 the Registrant updated his registration dossier with submission numbers [REDACTED] and [REDACTED].

The ECHA Secretariat considered the Registrant's updates and did not amend the draft decision.

On 5 March 2015 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 regarding effects on sediment organisms

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

- Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.); using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233).

Pursuant to Articles 41(1), 41(3), 10(b) and 14 as well as Annex I of the REACH Regulation, once the results of the above long-term sediment study are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the sediment PNEC.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request in this decision, or to fulfil otherwise the information requirement with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall to ECHA by **29 April 2016** an update of the registration dossier containing the information required by this decision.

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.

Information in the technical dossier regarding effects on sediment

Pursuant to Articles 10(a)(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.

Long-term toxicity to sediment organisms (Annex X Section 9.5.1.)

"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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant has sought to adapt the long-term toxicity testing on sediment organisms using the following justification: "*Ecotoxicological data for this substance includes acute and chronic studies for three trophic levels. All of the aquatic toxicity results indicate that there is no toxicity at the limit of water solubility. The substance is also readily biodegradable. For these reasons it is believed that the ecotoxicity of the substance is well defined and according to column 2 of Annex IX the equilibrium partitioning method is being used to assess the hazard to sediment organisms.*"

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on sediment organisms further due to no effects having been observed in aquatic studies and the substance being readily biodegradable. He justifies this conclusion further by explaining that he has used the equilibrium partitioning method (EPM) according to Column 2 of Annex IX to derive a PNEC_{sediment} screen.

ECHA points out that the justifications provided by the Registrant refer to column 2 of Section 9.4 of Annex IX to the REACH Regulation ("Effects on terrestrial organisms") and as such are not relevant for the present endpoint (long-term toxicity to sediment organisms, Section 9.5.1 of Annex X to the REACH Regulation).

ECHA notes further that in order for an adaptation of Annex X, 9.5.1. Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the Chemical Safety Report (CSR) that the conditions of an adaptation possibility (Annex XI) are fulfilled. In establishing this, in some cases and as explained in ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7.), Registrants may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

However, according to ECHA *Guidance on information requirements and chemical safety assessment* (R.7.B, version 1.2. November 2012, Section R.7.8.7., p. 140) the EPM cannot be used in a weight of evidence approach for substances that are highly insoluble and for which no effects are observed in aquatic studies. For such substances at least one sediment study has to be performed. ECHA notes that as stated by the Registrant in the adaptation statement for sediment quoted above and as is also shown in the aquatic studies in the technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a reported water solubility of 0.005 mg/L ECHA considers that long-term sediment testing is indicated for the registered substance.

ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms (Annex XI, 1.2.). In fact, the present substance has a high potential to adsorb to sediment. Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

Therefore, ECHA notes that the Registrant has not justified an adaptation.

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:

- Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD 218) OR
- Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD 225) OR
- Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233)

Notes for consideration by the Registrant

The Sediment-water Chironomid toxicity using spiked sediment (OECD 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses. ECHA considers that it is the Registrant's responsibility to choose the most appropriate test protocol and to give a justification for the choice. The Registrant may carry out more than one of the sediment tests defined in Section II above if he considers that further testing is required. While ECHA at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

Furthermore, both water and sediment exposure scenarios are described in the OECD 233 Test Guideline. The Registrant is advised to consult the OECD 233 Test Guideline and the ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

IV. Adequate identification of the composition of the tested material

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

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested 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.

Furthermore, 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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