EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003196-74-05/F Helsinki, 7 June 2013

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

For Dibutyltin oxide, CAS No 818-08-6 (EC No 212-449-1), 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 dossier for Dibutyltin oxide, CAS No 818-08-6 (EC No 212-449-1) submitted by [redacted] (Registrant).

This decision is based on the registration dossier 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 after 18 January 2013, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 28 May 2012 and is targeted at the technical dossier information for the standard information requirements of section 9 of Annexes IX to X (Ecotoxicological information) of the REACH Regulation.

On 4 September 2012 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 3 October 2012 the Registrant provided to ECHA comments on the draft decision, and on 21 November 2012 the Registrant updated the dossier.

ECHA considered the Registrant's comments received. On basis of the comments and the update dossier, Section II was amended by removing the request for information on substance identity. Section III was amended accordingly. Furthermore, based on the Registrant's comments, the timeline is Section II was amended and section III was modified accordingly.

On 18 January 2013 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 submitted proposals for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

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

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 15 March 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 25 April 2013.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

1) Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the test method as indicated on:

   a. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5., test method: *Daphnia magna* reproduction test EU C.20/OECD 211);
   b. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210);
   c. Bioaccumulation in aquatic species (Annex IX, 9.3.2., test method: Bioaccumulation in Fish: Dietary Exposure Bioaccumulation Fish Test, OECD 305-III;
   d. Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);
   e. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222 or test method: Enchytraeid reproduction test, OECD 220, or test method: Collembolan reproduction test in soil, OECD 232);
   f. Long-term toxicity testing on plants (Annex X, 9.4.6; test method: Terrestrial plants, growth test, OECD 208 with at least six species - two monocotyledonous and four dicotyledonous - tested or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants – ISO 220300); and
   g. Long-term toxicity to sediment organisms (Annex X, 9.5.1; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218 or test method: Sediment-water *Lumbriculus* toxicity test using spiked sediment, OECD 225).

Before conducting any of the tests mentioned above in points 1)a and 1)b the Registrant shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 1.1, May 2008), Chapter R7b, section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish. Furthermore, the same Guidance (section R.7.11.6) also needs to be consulted on the sequence of the terrestrial toxicity tests in points 1)d, e and f.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **7 June 2015**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of more than 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and/or with Annexes VI, IX, and X thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to endpoints

Pursuant to Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities 1000 tonnes or more per year shall contain as a minimum the information specified in Annex X of the REACH Regulation. The technical dossier contained adaptations to the standard information requirements for the endpoints on:

a. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5) and
b. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1).

According to column 1 of sections 9.1.5 and 9.1.6 of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and fish is required to fulfil the standard information requirements. The Registrant proposed an adaptation statement indicating that "*no direct exposure and only low indirect exposure is likely, whereas the chemical safety assessment concluded that the substance is of no immediate concern to the environment. The available data are adequate for classification and labelling purposes and PBT assessment, so no further testing is required*".

ECHA notes that the screening study for biodegradation in water that is present in the registration dossier showed that 0% degradation took place after 28 days, whilst the hydrolysis study was waived based on arguments concerning technical feasibility. The registered substance therefore meets the REACH Annex XIII criteria for persistence, P. The chemical is used for a wide range of industrial, professional and consumer applications with a main function as a catalyst in adhesives, coatings and paints. With a water solubility value of 4 mg/L, as described by the Registrant in the technical dossier, exposure of the aquatic compartment is, therefore, not unlikely.

Furthermore, the acute aquatic toxicity studies present in the dossier revealed considerable toxicity (EC50 values generally between 1 and 3 mg/L), without any marked sensitivity difference between daphnia and fish. Additionally, there are concerns for the substance's bioaccumulation potential (see point c. Bioaccumulation in aquatic species). Finally, the OECD SIDS Initial Assessment Report for SIAM 23 (October 2003) concluded that the chemicals in the dibutyltin category are candidates for further work due to their hazardous properties towards aquatic organisms.

For these reasons, ECHA believes that the waiving arguments of the Registrant are not adequate as the chemical safety report (CSR) does not provide the evidence to omit long-term aquatic testing. The information on the endpoints Long-term toxicity on aquatic invertebrates and Long-term toxicity to fish is, thus, not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to provide information for these endpoints.

Therefore, the Registrant is required to carry out the proposed studies: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5; test method: *Daphnia magna* reproduction test, EU C.20/ OECD 211) and Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1; test method: Fish, early-life stage toxicity test, OECD 210), using the registered substance subject to the present decision. As stated in section II above, the ECHA Guidance on information requirements and chemical safety assessment detailing the integrated testing strategy for aquatic toxicity needs be consulted in order to assess the necessity to conduct long-term toxicity testing on fish. Finally, for the correct interpretation of the test results, the Registrant shall consider the substance's behaviour in water (hydrolysis, precipitation, solubility) when selecting an appropriate analytical technique.

c. Bioaccumulation in aquatic species (Annex IX, 9.3.2)

According to section 9.3.2 of Annex IX of the REACH Regulation, bioaccumulation in aquatic species is required to fulfil the standard information requirements. The Registrant, in his updated dossier, proposed a weight-of-evidence approach referring to two published studies by Tsuda *et al.* that resulted in low bioconcentration factors for a read-across substance Dibutyltin dichloride (hereinafter "DBTC"), in order to justify the omission of further testing for the bioaccumulation endpoint.

In assessing whether a substance meets the conditions for read-across pursuant to the criteria laid down in Annex XI, Section 1.5 of the REACH Regulation, ECHA first has to examine whether the Registrant has provided adequate and reliable documentation supporting the read-across method. Only thereafter can ECHA fully examine whether the criteria of structural similarity and predictability of the effects from the reference substances have been fulfilled. Indeed, in cases where the documentation supporting a read-across approach is not adequate or reliable, ECHA will not be in a position to evaluate the overall read-across approach, and consequently will be unable to verify that there is compliance with the rules of Annex XI. Weight-of-evidence also requires adequate and reliable documentation to be provided.

In this case the Registrant included two literature studies on the same read-across substance (DBTC) referring to registered (DBTO) and analogue substances (DBTC) as structurally similar. The Registrant also referred to the fact that DBTC hydrolyses very rapidly in water to give the DBT moiety.

ECHA notes that the dossier does not present any other scientific explanation for the proposed read-across, nor does it contain any documentation to justify why REACH Annex XI, 1.5. criteria may apply. Specifically, the claim of the Registrant of the 'very rapid' hydrolysis is not substantiated (with quantitative or experimental data) and there is no information on the hydrolysis rate of DBTC to DBTO under experimental or field conditions. Furthermore, the Registrant has not presented a comparison of relevant physico-chemical properties for DBTC and DBTO linked to their environmental fate (for example, solubility, partition coefficients, etc.) and, specifically, to their bioaccumulation potential.

Therefore, due to the poorly documented scientific argumentation for the proposed read-across, ECHA considers that the REACH Annex XI, 1.5 criteria have not been fulfilled.

Additionally, both Tsuda *et al.* studies are reliability 4 (not assignable), non-Guideline studies and in the Registrant's own words "*No appropriate data that was judged to be both reliable and relevant to the material itself was uncovered. However studies were available on a closely related substance (dibutyltin dichloride) and although individually neither of these studies is considered adequate to wholly address this endpoint, it is considered that together they provide sufficient weight of evidence to qualitatively conclude the bioaccumulation potential of the substance. Both of the studies by Tsuda et al are considered to have been conducted to methods that deviate from the strict terms of the appropriate OECD guideline, and the parameters of the study were not wholly comparable to those required for accurate assessment of this data requirement. The studies were correspondingly assigned a reliability score of 4 (not assignable); this was based on methodological deficiencies and certain areas lacking in detail in the reporting of the studies*".

Therefore, as the read-across approach has not been sufficiently justified by the Registrant and due to the poor scientific quality of the proposed literature studies with the analogue substance DBTC, ECHA cannot accept the proposed information on its own or as part of a weight of evidence approach. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

The REACH Guidance recommends the Fish Dietary Accumulation test for certain types of substances due to their specific physical chemical properties (e.g. low water solubility, high Log Kow value). No Log Kow value has been presented in the dossier, but the OECD 305 guidance further clarifies that other suitable information on partitioning behaviour such as the Koc can be used for triggering the dietary bioaccumulation study. In the Chemical Safety Report, the Registrant uses a LogKoc value of higher than 6 for the PNEC derivation, which indicates very strong sorption.

Taking into account the properties of the substance and the potential technical feasibility issues for performing a flow-through test as also recognised by the Registrant in the comments to the Proposal for Amendment, the Registrant shall perform the bioaccumulation testing in fish following the OECD 305-III Guideline: Bioaccumulation in Fish: Dietary Exposure Bioaccumulation Fish Test.

d. Effects on soil micro-organisms (Annex IX, 9.4.2.);
e. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.) and
f. Long-term toxicity testing on plants (Annex X, 9.4.6.)

According to Annex IX, section 9.4.2, Annex X, section 9.4.4 and Annex X, section 9.4.6 of the REACH Regulation, effects on soil micro-organisms, long-term toxicity on terrestrial invertebrates and long-term toxicity testing on plants are required to fulfil the standard information requirements. According to Annex IX and X, section 9.4, column 2, the studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.

The Registrant has waived testing on terrestrial organisms arguing that "*Since no direct releases to soil from point sources of the substance in question are known, no significant exposure of the terrestrial compartment is expected. In addition the chemical safety assessment concludes that the substance is of no immediate concern to the environment. The available data are adequate for classification and labelling purposes and PBT assessment, so no further testing is required. Also direct and indirect exposure of the soil is unlikely.*"

ECHA notes that the chemical is persistent (0% degradation in 28 days), toxic to aquatic organisms (acute toxicity 1-3 mg/L), highly sorptive (Log K_{OC}> 6), whilst information on the bioaccumulation potential (Log BCF = 4.80 from the OECD SIDS report) is still not conclusive. Due to these properties, ECHA considers that according to the ECHA Guidance on information requirements and chemical safety assessment section R.7.11.6., the substance can be considered as a Hazard Category 4. The recommendation of the Guidance is not to perform a screening assessment based on the Equlibrium Partitioning Method (EPM), but rather to conduct long-term toxicity tests according to the standard information requirements of Annex X and choose the lowest value to derive the PNEC soil. This is also in line with the Annex IX, 9.4 column 2 recommendation that "*for substances with a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term. The choice of the appropriate tests depends on the outcome of the chemical safety assessment*".

Concerning the adaptation statement proposed by the Registrant, ECHA notes that the substance's partitioning and use patterns reveal that exposure of the terrestrial environment is not unlikely. Furthermore, Risk Characterisation Ratios (RCRs) of up to [redacted] have been calculated for soil for the exposure scenario referring to consumer use. The waiving statement can, therefore, not be accepted. In addition, caution should be taken when applying the EPM for highly sorptive (i.e. Log K_{OC} > 6) and organometallic substances (Guidance on information requirements and chemical safety assessment, version May 2008, Chapter R.10).

The information on these endpoints is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for these endpoints by carrying out the following studies:

- Effects on soil micro-organisms (Annex IX, 9.4.2, EU C.21/OECD 216);
- Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4, OECD 222 or OECD 220 or OECD 232); and
- Long-term toxicity on plants (Annex X, 9.4.6, ISO Method 22030 or OECD 208).

Concerning the long-term toxicity testing on terrestrial invertebrates, the earthworm reproduction test (OECD 222), the Enchytraeid reproduction test (OECD 220) and the Collembolan reproduction test (OECD 232) are each considered capable of generating information that is appropriate for the fulfilment of the information requirements of Annex X, section 9.4.4 under REACH. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Concerning the long-term toxicity testing on terrestrial plants, the OECD test guideline 208 reflects on the need to choose the number of species to be tested depending on relevant regulatory requirements and on the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing ECHA considers six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. The Registrant should consider if testing on additional species is needed to cover the information requirement.

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

According to column 1 of section 9.5.1 of Annex X of the REACH Regulation, long-term toxicity to sediment organisms is a standard information requirement. The Registrant has omitted testing on sediment organisms arguing that "*In accordance with column 2 of REACH Annex X, Long-term Toxicity to Sediment Organisms testing does not need to be conducted as sediment PNECs have been calculated by the equilibrium partitioning method and the chemical safety assessment concludes that the substance is of no immediate concern to the environment. The available data are adequate for classification and labelling purposes and PBT assessment, so no further testing is required. Also direct and indirect exposure of the sediment is unlikely*".

As explained before, the chemical is very persistent (0% degradation in 28 days), toxic to aquatic organisms (acute toxicity 1-3 mg/L), highly sorptive (Log K_{OC}> 6), whilst information on the bioaccumulation potential (Log BCF = 4.80 from the OECD SIDS report) is still not conclusive. Furthermore, the substance's partitioning and use patterns reveal that exposure of the sediment compartment is not unlikely, with RCRs of up to [redacted] calculated for the exposure scenario referring to consumer use. The waiving statement can, therefore, not be accepted. In addition, caution should be taken when applying the EPM for highly sorptive (i.e. Log K_{OC} > 6) and organometallic substances (Guidance on information requirements and chemical safety assessment, version May 2008, Chapter R.10).

The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is required to carry out the proposed study: Long-term toxicity testing on sediment organisms (Annex X, 9.5.1) according to OECD 218 (Sediment-water Chironomid toxicity test using spiked sediment) or OECD 225 (Sediment-water *Lumbriculus* toxicity test using spiked sediment). When selecting the most appropriate test method, the Registrant should consult the Guidance on information requirements and chemical safety assessment, Chapter R.7b (R.7.8.9). Finally, for the correct interpretation of the test results, the Registrant shall consider the substance's behaviour in water (hydrolysis, precipitation, solubility) when selecting an appropriate analytical technique.

2) Registrant's comments

In his comments to the draft decision, the Registrant agreed to the need to conduct further studies on daphnia, soil micro-organisms and terrestrial invertebrates. Furthermore, he argued that further tests on fish and terrestrial plants should only be performed after conducting the above-mentioned studies. ECHA believes that the current draft decision already provides for the need and sequence of the aquatic and terrestrial toxicity studies and decided not to amend Section II the draft decision. The same applies for the toxicity testing on sediment organisms, as rules for adaptation in Annex X, 9.5.1, column 2 are not met as outlined above in 1)g.

Concerning the need for a bioaccumulation study, the Registrant presented a weight-of-evidence approach to argue that such testing is not needed. ECHA does not agree with the Registrant's argumentation for the reasons already presented in the draft decision and because of the need to unequivocally conclude on the potential PBT and/ or vPvB status of the substance.

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 18 months from the date of adoption of the decision. However, during the 30-day commenting period, the Registrant provided substance-specific and technical feasibility argumentation in order to justify why the proposed 18 months may not be sufficient to allow the successful completion of the bioaccumulation study on the registered substance. ECHA accepts the argumentation of the Registrant and considers that a reasonable time period for providing all required information in the form of an updated IUCLID5 dossier is 24 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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 studies 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 studies 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 studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies 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 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://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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