EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000001797-62-07/F Helsinki, 5 April 2012

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

For [redacted] master Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexyl ester, CAS [redacted] (EC No 443-860-6), 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 (the REACH Reg ulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation, ECHA has performed a compliance check of the registration dossier for [redacted] ***master Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexyl ester***, CAS [redacted] (EC No. 443-860-6) submitted by [redacted] (the "Registrant"), latest submission number [redacted] for [redacted].

The compliance check was initiated on 27 May 2010.

On 29 April 2011 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 30 May 2011 the Registrant provided to ECHA comments on the draft decision.

On 30 June 2011 the Registrant submitted an updated dossier to ECHA.

ECHA took into account the information received and amended the draft decision where relevant.

On 4 November 2011 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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

On 8 December 2011 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 within 30 days of the receipt of the notification.

On 19 December 2011, the draft decision was referred to the Member State Committee.

On 9 January 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.
After discussion in the Member State Committee meeting on 6-10 February 2012, the Member State Committee further modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 9 February 2012.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a) and (b), 41(3), 3(28), 10(a)(vii), 12(1)(d) and 13 as well as Annexes IX and XI of the REACH Regulation, the Registrant shall submit the information using the test method as indicated on
   a. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to terrestrial plants: OECD guideline 208 or ISO standard 22030); and
   b. Effects on terrestrial organisms (Annex IX, 9.4.; Test on effects on soil micro-organisms: EU Method C.21).

2) Pursuant to Articles 41(1)(c), 41(3), 10(b), and 14, and Annex I of the REACH Regulation, the Registrant shall submit the missing information related to Chemical Safety Report (CSR) and update the CSR accordingly.

   a. Identification of the PNECsoil (Annex I, 3.3.1.);
   b. Exposure assessment and risk characterisation for environment, including the waste stage (Annex I, sections 5 and 6).

3) Pursuant to Articles 41(1)(a), 41(3), and Article 10 as well as Annex VI of the REACH Regulation, the Registrant shall submit the following information:

   a. Waste from production and use (Annex VI, 3.6 and Note 1): submit the information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses. Alternatively, clearly state why no waste is expected during all stages of the life-cycle (manufacture and identified uses) (Annex VI, 3.6 and Note 1) and update section 3.7 of the IUCLID dossier accordingly;
   b. Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2): provide an updated robust study summary for bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2) for the bioaccumulation test ("[redacted]" in IUCLID section 5.3.1), including clear results tables and the '*Applicant's summary and conclusion*'. For the screening test mentioned in the CSR, a robust study summary shall be given in the IUCLID dossier.

4) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii) and Article 12(1)(d) as well as Annexes I and IX of the REACH Regulation, the Registrant shall include in the dossier a robust study summary of long-term toxicity testing on invertebrates (*Daphnia*) performed on the substance [redacted] and received by the [redacted] Competent Authority on 2 July 2007 (Annex IX, 9.1.5, OECD 211).

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 **5 April 2013**.

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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 ,13 and 14 and with Annexes I, VI, VIII, IX and XI 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), 12(1)(d) and 13 as well as Annexes VII to IX of the REACH Regulation, a registration for a substance produced in quantities of 100 – 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII and VIII and testing proposals for the provision of information specified in Annex IX of the REACH Regulation.

a. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to terrestrial plants: OECD guideline 208 or ISO standard 22030)); and
b. Effects on terrestrial organisms (Annex IX, 9.4.; Test on effects on soil micro-organisms: EU Method C.21).

a. Effects on terrestrial organisms (Annex IX, 9.4.; Test on toxicity to terrestrial plants: OECD guideline 208 or ISO standard 22030)

The Registrant has waived test on short-term toxicity to plants based on the following justification: "*Direct exposure to the terrestrial compartment is not intended. An indirect exposure to the soil compartment via sewage sludge can not be excluded, however, due to the low water solubility, the low bioavailability and the low bioaccumulation potential in fish (BCF: 166.8) along with to the absence of any acute and chronic aquatic toxicity, effects on terrestrial organisms are very unlikely..*". The Registrant concludes that tests on terrestrial invertebrates (macro-organisms and arthropods) and plants can be waived.

ECHA points out that this reasoning does not comply with the adaptation rules set out in Annex IX, 9.4, column 2 concerning this endpoint nor Annex XI, section 1 governing adaptations on scientific basis:

(i) the fact that direct exposure is not "*intended*" does not follow column 2 waiving which requires 'unlikely' exposure both for direct and indirect exposure;
(ii) low water solubility and low bioavailability for fish are not acceptable as waiving arguments for soil, but are rather indications for the need to investigate the soil and sediment compartment;
(iii) low bioaccumulation in fish is questionable as long as concerns with the reported fish BCF study have not been clarified;
(iv) the Registrant has not justified why he considers the absence of effects at water solubility limit for algae, fish (acute) and daphnids (acute and long-term) to be predictive of the absence of effects on terrestrial organisms;
(v) "*the lack of chronic aquatic toxicity*" has not been fully shown: it has not been proven that dapnids are more sensitive than fish; and

(vi) the substance is poorly degradable ('persistent' and 'very persistent' accepted for all compartments by the Registrant in the CSR) and highly sorptive. Therefore, according to column 2, the Registrant should have considered long-term testing on terrestrial organisms.

Therefore, the Registrant shall perform a study according to OECD guideline 208 or ISO standard 22030.

b. Effects on terrestrial organisms (Annex IX, 9.4.; Test on effects on soil micro-organisms: EU Method C.21).

The Registrant has waived test on effects on soil micro-organisms based on the lack of effects in aquatic micro-organisms. The provided justification is not acceptable for this endpoint: the absence of effects on aquatic micro-organisms is not predictive for the absence of effects in soil micro-organisms. ECHA considers that the test on effects on soil micro-organism is important given the high log Koc and lack of degradability of the substance. In addition, the Registrant has not provided any justification that would qualify the adaptation on the basis of Annex IX, 9.4., column 2 or Annex XI.

Therefore, the Registrant is requested to provide the information on test on effects on soil micro-organisms using the test method EU Method C.21.

The Registrant is accordingly requested to submit the information for the above endpoints performed with the registered substance.

2) Missing information related to Chemical Safety Report

According to Articles 10(b) and 14 of the REACH Regulation, a chemical safety report (CSR) is required at the present tonnage level. Annex I sets out the general provisions for assessing substances and preparing CSR.

a. Identification of the PNECsoil (Annex I, 3.3.1.)

Articles 10(b) and 14 as well as Annex I, 3.3 of the REACH Regulation provide that the PNEC (Predicted No-Effect Concentration) for each environmental sphere shall be established. The PNEC for soil is missing in the dossier and the Registrant is requested to derive the PNECsoil using the results of the data of the studies under Annex IX, 9.4.1, 9.4.2, and 9.4.3 requested under point 1a above. The Registrant is requested to update the dossier (IUCLID file and CSR) accordingly.

b. Exposure assessment and risk characterisation for environment, including the waste stage (Annex I, sections 5 and 6)

According to Articles 10(b) and 14(4) of the REACH Regulation, an exposure assessment and risk characterisation shall be included in the chemical safety assessment if the substance meets the criteria for classification as dangerous under Directive 67/548/EEC (from 1 December 2010, replaced by the criteria for the hazard classes and/or categories specified in Article 58(1) of Regulation (EC) No 1272/2008) or the PBT/vPvB criteria according to Annex XIII to the REACH Regulation.

The registered substance is classified as R53 in Annex I to Directive 67/548/EEC, and is included in Annex VI, table 3.1 to the Regulation (EC) No 1272/2008 (CLP) (Aquatic Chronic 4, H413). In the CSR, no exposure scenario or exposure estimation has been provided although the substance is classified.

Article 14(4) and Annex I, 5.0 and 5.2.2 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment "*...shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses...*" , including the waste stage and shall cover any exposures that may relate to the identified hazards. A risk characterisation is required under Annex I, section 6 to be carried out for each exposure scenario.

The Registrant is accordingly requested to perform an exposure assessment for the environment, including the generation of exposure scenarios and exposure estimations together with risk characterisation including waste stage and to update the CSR.

3) Other missing information

a. Waste from production and use (Annex VI, 3.6 and Note 1)

According to Article 10(a)(iii) and Annex VI, 3.6 of the REACH Regulation, information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses should be provided. In section 3.7 of the IUCLID, the Registrant states: "Waste quantity (substance): No information available" and "Waste quantity resulting from use (preparation): not applicable". The Registrant has not justified this. However, the Registrant states in section 2.2 of the CSR that substance is used [redacted]. As waste may presumably be generated in this use, it is not clear why waste is "not applicable" and therefore, the dossier is not in line with Annex VI, Note 1.

Accordingly, the Registrant shall update section 3.7 of the IUCLID dossier and provide information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses. Alternatively, he can clearly state why no waste is expected during all stages of the life-cycle (manufacture and identified uses).

b. Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2)

According to Articles 10(a)(vii) and 111 of and Sections 1.1.4 and 3.1.5 of Annex I to the REACH Regulation, a technical dossier that is in the IUCLID format shall include robust study summaries of all key data used in the human health and environmental hazard assessment. Under Article 3(28), the robust study summary shall include a "detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report."

The Registrant has not reported in the IUCLID format a robust study summary within the meaning of Article 3(28) of the REACH Regulation for the bioaccumulation study (IUCLID section 5.3.1). In particular, the table in the Results and Discussion section under '*Any other information on results incl. tables*' is not clear, especially the concentration of the substance in water and tissue at the different sampling times. The '*Applicant's summary and conclusion*' has not been filled in.

Further, the study [redacted] mentioned in the CSR on p. 13, Table 13 and on p. 14, section 4.3.3 is not present in the IUCLID dossier. This screening study (Klimisch score 2 according to the Registrant) is qualified as 'disregarded' in Table 13 of the CSR, but is used in the weight of evidence approach in the summary of the Bioaccumulation: aquatic / sediment summary of IUCLID section 5.3.1 and on p.14, section 4.3.3 of the CSR. If this study is used in the weight of evidence approach presented by the Registrant, a robust study summary should be available in the IUCLID file.

Therefore, the Registrant is required to provide an updated robust study summary for the bioaccumulation test ("[redacted]" in IUCLID section 5.3.1), including clear results tables and the '*Applicant's summary and conclusion*'. For the screening test mentioned in the CSR, a robust study summary shall be given in the IUCLID dossier.

Further guidance can be found in the *Information requirements Manual 1 Requirements for Robust Study Summary* published on the website at:
http://echa.europa.eu/doc/publications/practical_guides/pg_report_robust_study_summaries.pdf

4) Missing robust study summary on long-term toxicity testing on invertebrates (*Daphnia)*

Pursuant to Article 12 of the REACH Regulation, the technical dossier shall include all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant. According to Annex I, section 3.1.1. the environmental hazard identification shall be based on all available information.

The substance was previously notified by the Registrant to the [redacted] Competent Authority and OECD 211-study (long-term toxicity testing on invertebrates (*Daphnia)*) was then formally requested in a decision dated 26.06.2006, according to Article 7(2) of Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended). The study was performed by the Registrant and submitted to [redacted] Competent Authority and subsequently the results were considered in the risk assessment. Therefore the study on *Daphnia* is indeed available to the Registrant and relevant for the substance and as such it should be present in the dossier.

Moreover, the Registrant is reminded of the obligation stemming from Annex I, section 3.1.5. of the REACH Regulation that the study giving rise to the highest concern shall be used to draw a conclusion (i.e. used as a key study) for the environmental hazard assessment part of CSR. If the study giving rise to the highest concern is not used, then this shall be fully justified and included as part of the technical dossier.

ECHA points out that the [redacted] Competent Authority indicated in its proposal for amendment that the missing long-term toxicity testing on invertebrates (*Daphnia)* is the study giving rise to the highest concern.

Thus, it is essential that robust study summary of long-term toxicity testing on invertebrates (*Daphnia)*is included in the dossier and that this new data is taken into account for the environmental hazard assessment, in accordance with Annex I, section 3.1.5. of the REACH Regulation.

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

ECHA always reminds Registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

"*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

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 the technical progress or other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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://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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