EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003570-80-05/F Helsinki, 11 November 2013

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

For 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether, CAS No 51-03-6 (EC No 200-076-7), 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 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether, CAS No 51-03-6 (EC No 200-076-7) submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of [redacted]. This decision does not take into account any updates after 20 June 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 from initiating further compliance checks on the registration at a later stage.

The compliance check was initiated on 05 December 2012.

On 26 April 2013 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]

On 27 May 2013 ECHA received comments from the Registrant. The ECHA secretariat did not amend the draft decision based on Registrant's comments.

On 20 June 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, a Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 26 July 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.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 5 August 2013 ECHA referred the draft decision to the Member State Committee.

On 26 August the Registrant submitted comments on the proposal for amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 9 September 2013 in a written procedure launched on 29 August 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)(vii), 12(1)(a), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information using the test method as indicated on:

   a. Melting/freezing point (Annex VII, 7.2.; test method: EU A.1./OECD 102);

2) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vii), 3(28), 13(3) and 111 as well as Sections 1.1.4. and 3.1.5. of Annex I to the REACH Regulation, the Registrant shall provide in the IUCLID format a robust study summary for key studies concerning the following endpoints, as specified in section III.2) below:

   a. Sediment simulation testing (Annex IX, 9.2.1.4.)
   b. Soil simulation testing (Annex IX, 9.2.1.3.)
   c. Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.)
   d. Long-term toxicity testing on fish (Annex IX, 9.1.6.)
   e. Long-term toxicity testing on invertebrates (Annex IX, 9.1.5.)
   f. Growth inhibition study aquatic plants (algae preferred) (Annex VII, section 9.1.2.)
   g. Short-term toxicity to plants (Annex IX, Section 9.4.3.)
   h. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.)
   i. Repeated dose toxicity studies (Annex IX, 8.6. (inhalation))
   j. Carcinogenicity study (Annex X, 8.9.1.)
   k. Two-generation reproductive toxicity study, one species, (Annex IX, 8.7.3.)
   l. Pre-natal developmental toxicity study, one species, (Annex IX: 8.7.2.)

3) Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 3(29), 13(3) and 111, the Registrant shall provide in the IUCLID format a study summary for supporting studies concerning the following endpoints, as specified in section III.3) below:

   a. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.)
   b. Carcinogenicity study (Annex X, 8.9.1.)
   c. Pre-natal developmental toxicity study, one species, (Annex IX, 8.7.2.)

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the above information in the form of an updated registration to ECHA by **11 February 2014.**

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 [redacted] in accordance with **Article 6 and 11(2)** of the REACH Regulation, does not comply with the requirements of Articles **10, 12 and 13 and with Annexes I, VI, VII, VIII and IX** 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 melting/freezing point

Pursuant to Articles 10(a)(vii) and 12(1)(d) of the REACH Regulation, a registration for a substance produced in quantities of [redacted] per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

The technical dossier contains an adaptation to the standard information requirement for melting/freezing point.

According to column 1 of section 7.2. of Annex VII of the REACH Regulation, a study on melting/freezing point is required to fulfil the standard information requirements. Column 2 of Section 7.2. of Annex VII further indicates that the study does not need to be conducted below a lower limit of -20 °C.

ECHA observes that the Registrant has sought to use the Column 2 adaptation to fulfil this information requirement by indicating under IUCLID section 4.2. Melting point/freezing point that "Practical experience has shown that the purified active substance Piperonyl butoxide is a liquid both at ambient temperature and even at -10°C". Since the Registrant has not considered the substance melting/freexing point to the lower limit of -20 °C as required to adapt the standard information requirement as specified in Column 2 of section 7.2. of Annex VII, ECHA considers the waiving statement submitted not acceptable.

Therefore, the Registrant is requested to submit the following information derived with the registered substance subject to present decision: Melting/freezing point (Annex VII, 7.2.; test method: EU A.1./OECD 102).

2) Missing robust study summaries on several endpoints

Annexes VII to IX to the REACH Regulation specify the standard information requirements for a registration for a substance produced in quantities of [redacted] per year. In addition, according to Annex IX, second introductory paragraph, any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

According to Articles 10(a)(vii) and 111 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."

For the endpoints listed under Section II 2) a to l above, the Registrant has not reported in the IUCLID format adequate robust study summaries (RSS) within the meaning of Article 3(28) of the REACH Regulation for the studies marked as key studies. Therefore the submitted technical dossier does not provide sufficient information to allow an independent assessment of the studies.

For the endpoints listed under Section II 2) a-l the following information shall especially be reported on the respective study marked as a key study:

a. Sediment simulation testing (Annex IX, 9.2.1.4.)
    i. Results for reference substance
    ii. Information on whether validity criteria fulfilled or not
    iii. Identity of metabolites M1 and M2
b. Soil simulation testing (Annex IX, 9.2.1.3.)
    i. Information on study design
    ii. Results for recovery rates, mineralization, parent compound, non-extracatbale residues, metabolites
    iii. Information on degradation pathway and degradation kinetics
    iv. Information on microbial viability
c. Bioaccumulation in aquatic species, preferably fish (Annex IX, 9.3.2.)
    i. Information on study design
    ii. Study organisms specific details (acclimation, duration of uptake and depuration phases, feeding)
    iii. Information on correction for growth dilution
    iv. Why the validity criteria was judged as having been fulfilled
d. Long-term toxicity testing on fish (Annex IX, 9.1.6.)
    i. Information on study design
    ii. information on whether validity criteria of maintaining substance concentrations within 20 % fulfilled
    iii. Detailed results
    iv. Study organisms specific information such as details on number of average days to hatch, number of fertilised eggs and hatched fish, data on fish length and weight
    v. Information on control survival
    vi. Why the vailidty criteria was judged as having been fulfilled
e. Long-term toxicity testing on invertebrates (Annex IX, 9.1.5.)
    i. Clear, separate information on the range finding test and the actual standard study
    ii. detailed results (both for controls and the study vessels)
    iii. information on whether validity criteria fulfilled or not
f. Growth inhibition study aquatic plants (algae preferred) (Annex VII, section 9.1.2.)
    i. Details on test conditions
    ii. detailed results and growth curves
    iii. if solvent controls were used
    iv. Why the validity criteria was judged as having been fulfilled (was there exponential growth in controls and sample vessels?)
g. Short-term toxicity to plants (Annex IX, Section 9.4.3.)
    i. Details on study design

ii. Information on controls
iii. Detailed results and effect values
iv. Why the validity criteria was judged as having been fulfilled

h. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.)
   i. RSS as required for IUCLID format as specified in the ECHA Practical Guide 3 section 5.3. Repeated dose toxicity
i. Repeated dose toxicity studies (Annex IX, 8.6.)
   i. RSS as required for IUCLID format as specified in the ECHA Practical Guide 3 section 5.3. Repeated dose toxicity
   ii. Detailed results and result tables for the inhalation study
j. Carcinogenicity study (Annex IX, second introductory paragraph; Annex X, 8.9.1.)
   i. Detailed explanation on conflicting results obtained from the key studies and the supporting studies
k. Two-generation reproductive toxicity study, one species (Annex IX, 8.7.3.)
   i. Detailed results including result tables that list the parental and offspring parameters per dose group
l. Pre-natal developmental toxicity study, one species (Annex IX: 8.7.2.)
   i. Detailed results providing the parameters specified in the test guideline (OECD 414) per treatment group

The Registrant shall therefore submit RSSs in IUCLID format for the endpoints listed which shall include the details indicated for each endpoint above to allow an independent assessment of the studies submitted. The Registrant should refer to ECHA Practical Guide 3 How to report robust study summaries (Version 2.0, November 2012) for detailed advice.

Notes for consideration by the Registrant:

The Registrant is reminded of the obligation imposed by Article 11 of the REACH Regulation on all the registrants of the same substance to submit registrations for the same substance jointly.

In addition, the Registrant is reminded that the REACH Regulation foresees the sharing of information between registrants of the same substance. When exercising this, a registrant is – pursuant to Article 13(5) of the REACH Regulation – entitled to refer to study summaries and robust study summaries for the same substance submitted by another registrant of the same substance, provided that he can show that the substance is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

ECHA notes that in the Registrant's comments on a proposal for amendment it became apparent that the above notes (which were previously included under Section II of the decision) were misunderstood. ECHA, in order to clarify this aspect, notes that the present decision requires the submission of the robust study summaries of the studies reported by the Registrant addressed by the present decision. However, if for any endpoint the Registrant is unable to submit a robust study summary, he would have an information gap. In order to fulfil this information gap no new vertebrate animal tests should be proposed if data for the endpoint in question is available already and may be obtained through the data-sharing provisions.

3) Missing study summaries on several endpoints

Article 10(a)(vi) requires the registration dossier to include study summaries of the information derived from the application of Annexes VII to XI.

Under Article 3(29), the study summary shall include a "summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study."

For the following endpoints, the Registrant has not reported in the IUCLID format adequate study summaries within the meaning of Article 3(29) of the REACH Regulation for the studies marked as supporting studies:

a. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.)
    i. Detailed explanation why results are not seen biologically relevant
b. Carcinogenicity study (Annex X, 8.9.1.)
    i. Detailed explanation on conflicting results obtained from the key studies and the supporting studies
c. Pre-natal developmental toxicity study, one species, (Annex IX, 8.7.2.)
    i. Detailed results providing the parameters specified in the test guideline (OECD 414) per treatment group

Therefore the submitted technical dossier does not provide sufficient information to make an assessment of the relevance of the studies possible.

The Registrant shall therefore submit the study summaries with the above missing information in the IUCLID format for the endpoints listed under Section II 3) to make it possible to assess the relevancy of the studies submitted.

IV. Adequate identification of the composition of the tested material

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. endpoints indicated above.

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.

[redacted]

Jukka Malm
Director of Regulatory Affairs