Decision number: CCH-D-0000002030-95-06/F Helsinki, 18 July 2012

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

For tert-butyl hydroperoxide, CAS No 75-91-2 (EC No 200-915-7), 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 the ECHA has performed a compliance check of the registration dossier for tert-butyl hydroperoxide, CAS No 75-91-2 (EC No 200-915-7) submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for 1000 or more tonnes per year. This decision does not take into account any updates submitted after 20 January 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.

The compliance check was initiated on 26 October 2010.

On 26 October 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 24 November 2011, the Registrant provided comments on the draft decision to ECHA. ECHA has considered the information received and amended the draft decision accordingly.

On 20 January 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. Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify the draft decision.

On 23 February 2012, ECHA notified the Registrant of the 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.

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

On 19 March 2012 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 24-27 April 2012, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 26 April 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) and 10(a)(vi) and (vii) as well as Annexes IX and X of the REACH Regulation the Registrant shall carry out the following tests using the indicated test method for the registered substance:

   a. Viscosity (Annex IX, 7.17.; According to OECD Test Guideline 114);
   b. Sub-chronic toxicity study (90-day) in the rat by inhalation (Annex IX, 8.6.2.; EU Method B.29. or OECD 413);
   c. Carcinogenicity study in the rat by inhalation (Annex X, 8.9.1.; EU Method B.32 or OECD 451) unless the substance is classified as germ cell mutagen category 1A or 1B.

2) Pursuant to Articles 41(1)(c), 14 and Annex I of the REACH Regulation the Registrant shall submit the following information in the form of an updated chemical safety report:

   a. Derived No Effect Level for mutagenicity;
   b. Modelled and measured exposure data using the report of the risk assessment completed under Regulation (EEC) No 793/93 or scientifically supported justification for deviating from the risk assessment;
   c. Emission and exposure estimates during the waste life-cycle stage;
   d. Risk characterisation for the physicochemical properties of the substance.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information for 1a and 2a-d in the form of an updated IUCLID dossier to ECHA by **20 January 2014**.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information for 1b and 1c in the form of an updated IUCLID dossier to ECHA by **19 July 2016**.

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 1000 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12, 14 and with Annexes I, IX, X 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) and (vii), 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VI-X of the REACH Regulation.

(a) The technical dossier contained an adaptation to the standard information requirements for the endpoints on Viscosity (Annex IX, 7.17.). The Registrant has proposed that the study [is] technically not feasible, stating "TBHP is only available as an aqueous solution to maintain stability, therefore the viscosity test for TBHP itself is not possible." According to Annex XI, Section 2 of the REACH Regulation, testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance. However, Article 3(1) defines a substance to "mean[s] a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition". Since the registered substance contains [redacted]% water as an additive necessary to preserve its stability, the registered substance by definition contains [redacted]% water and may be tested in this form. Indeed, the Registrant notes that the substance is always produced, distributed, and used as a solution with a concentration of [redacted]% in water. Thus the proposed adaptation does not satisfy the requirements of Annex XI, Section 2 as the study can be done on the substance registered and none of the properties of the substance are such as to make the conduct of the study not technically possible. There is consequently an information gap for the endpoint of Annex IX, 7.17. of the REACH Regulation. The Registrant is accordingly requested to submit the information using the test method: Viscosity of liquids (OECD 114). The Registrant is requested to update the dossier with the relevant information.

(b) The technical dossier contained an adaptation to the standard information requirements for the endpoint on sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.). The Registrant has provided a waiver that the study is "scientifically unjustified". However, the argument advanced by the Registrant does not meet the specific rules for adaptation of the information requirements for repeated dose toxicity under column 2 of Annex IX, 8.6.2., nor the general rules for adaptation according to Annex XI of the REACH Regulation. There is therefore an information gap for the requirement of Annex IX, 8.6.2. The Registrant is accordingly requested to submit the information for sub-chronic toxicity study (90-day) in the rat by inhalation using the test method: EU method B.29 or OECD 413, in the rat. The Registrant is requested to update the dossier with the relevant information.

Additionally, ECHA reminds the Registrant that pursuant to Annex I, section 0.5 of the REACH Regulation, the Registrant, while waiting for the results of further testing, should record in the chemical safety report (CSR) the interim risk management measures he has put in place to manage the risks that are being explored. Specifically, as set out in the EU RAR, there is a need to address concerns arising from the mutagenicity of the compound. These concerns have been strengthened by the ability of the substance to induce local effects consistent with evidence of a carcinogenic process in the 28-day inhalation study performed by the Registrant after the publication of the EU RAR.

During the commenting period the Registrant provided comments for this endpoint, He argues that the effects from the 28-day inhalation study are consistent with irritancy/

corrosion, that duration of exposure is less important than vapour concentration, that a 90-day study would not provide additional information and that the waiving of such study is supported by ethical considerations. ECHA considered comments of the Registrant and maintains the opinion that the arguments provided do not meet the specific rules for adaptation of the information requirements for repeated dose toxicity under column 2 of Annex IX, 8.6.2., nor the general rules for adaptation according to Annex XI of the REACH Regulation. Therefore there is a need for testing (as requested) to fill in the gap for the requirement of Annex IX, 8.6.2. of the REACH Regulation.

(c) The technical dossier contains an adaptation to the standard information requirement for a carcinogenicity study (Annex X, 8.9.1.). The Registrant has provided a waiver based on "exposure considerations", but these do not meet the specific requirements of Annex XI or column 2 of Annex X, 8.9.1. of the REACH Regulation. Pursuant to Annex X, 8.9.1., a carcinogenicity study may be required by the ECHA in accordance with Articles 40 or 41 if: (i) the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure, and (ii) the substance is classified as germ cell mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.

In respect of the first criterion, the substance is used by workers, and there is evidence of frequent and long-term human exposure from Section 10.1 of the Chemical Safety Report.

In respect of the second criterion, the substance is classified as germ cell mutagen category 2, and there is evidence that the substance can induce hyperplasia in repeated-dose toxicity studies that are available for the registered substance in the technical dossier (28-day study in IUCLID section 7.5.2).

The substance therefore meets the criteria set out in column 2 of Annex X, 8.9.1. under which a carcinogenicity study may be required at the discretion of ECHA. ECHA has considered all relevant information, including the exposure of humans to the substance as set out in the Chemical Safety Report, and the full toxicological profile of the substance, with special reference to the genotoxicity and potential carcinogenicity of the substance, and ECHA considers that there is a concern about the carcinogenic potential of the substance which warrants the conduct of a carcinogenicity study. There is therefore an information gap for the information requirement of Annex X, 8.9.1. Exposure of humans via inhalation is likely taking into account the physicochemical properties of the substance and the exposure assessment in the Chemical Safety Report, and so the inhalation route is appropriate. Having regard to the likely route of human exposure and the toxicological concerns, ECHA considers that the inhalation route is the most appropriate route of exposure. The Registrant is accordingly requested to submit the information for a carcinogenicity study in the rat by inhalation (Annex X, 8.9.1.; EU Method B.32 or OECD 451). The Registrant is requested to update the dossier with the relevant information.

The carcinogenicity study shall not be performed if the substance is classified as germ cell mutagen category 1A or 1B in accordance with Regulation (EC) No 1272/2008.

Additionally, ECHA reminds the Registrant that pursuant to Annex I, section 0.5 of the REACH Regulation, the Registrant, while waiting for the results of further testing, should record in the chemical safety report (CSR) the interim risk management measures he has put in place to manage the risks that are being explored.

2) Missing information related to Chemical Safety Report (CSR)

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

Pursuant to Annex I, 0.5 of the REACH Regulation, where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified. The registered substance has been evaluated under risk assessments completed under Regulation (EEC) No 793/93 (report published 2008, referred further as EU RAR), so this assessment should be taken into account in relevant parts of the CSR. The Registrant has already referred to the data presented in the EU RAR in the CSR.

(a) Derived No Effect Level for mutagenicity

Annex I, section 1.4 of the REACH Regulation, requires the Registrant to establish derived no effect levels (DNEL(s)) for the registered substance. The Registrant considers that the substance meets the criteria for classification as Mutagenic category 2, according to CLP. However, the chemical safety report (CSR) under paragraph 5.11, Mutagenicity, does not contain a DNEL for effects on mutagenicity.

The Registrant is accordingly requested to establish the appropriate DNEL, in accordance with Annex I, section 1.4.1. of the REACH Regulation. Alternatively, if it proves not possible to derive a DNEL, then this shall be clearly stated and fully justified, in accordance with Annex I, section 1.4.2 of the REACH Regulation.
Additionally, the EU RAR report on tert-butyl hydroperoxide in respect of mutagenicity considers that TBHP is mutagenic to the sites of first contact, and that local carcinogenicity can not be excluded. The Registrant is accordingly requested, pursuant to Annex I, 0.5, to take into account this finding from the EU RAR and reflect it in the CSR, or provide scientific justification for deviating from this assessment.

(b) Modelled and measured exposure data using the report of the risk assessment completed under Regulation (EEC) No 793/93 or scientifically supported justification for deviating from the risk assessment

The EU RAR uses measured exposure data and uses EASE for the exposure model, whereas the Registrant uses a different exposure model (TRA) and does not use measured data. Pursuant to Annex I, 0.5, the Registrant should take into account the modelled and measured exposure data from the EU RAR and reflect it in the CSR, or provide scientific justification for deviating from this assessment.

(c) Emission and exposure estimates during the waste life-cycle stage

Articles 10(b) and 14(4) as well as Annex I, Section 5 of the REACH Regulation require generation of exposure scenarios and exposure estimations for the registered substance. Annex I, 5.2.2 sets out: "The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage."

Therefore, in the exposure estimation the Registrant has to consider and quantify exposure of humans and the environment arising from the emissions in the waste life-cycle stage.

ECHA notes that, according to the CSR provided by the Registrant, waste is expected to be generated. However, it is not specified what the possible releases and exposure levels of the substance to the environment are from these operations. Therefore, exposure assessment based on treatment technologies for the waste life-cycle stage is needed.

Accordingly, the Registrant shall provide emission estimates for the waste stage, with corresponding exposure estimates, and update the CSR accordingly.

(d) Risk characterisation for the physicochemical properties of the substance

Pursuant to Article 14(4)(b) and Annex I, 6.3 and 6.4 of the REACH Regulation, a risk characterisation is to be performed on the substance that fulfils the criteria for certain hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) or is assessed to be PBT or vPvB, and it shall consist of an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.
The substance is classified as a Flammable liquid Category 3, and and Organic peroxide Type F. However, the risk characterisation of the physicochemical properties of the registered substance has not been carried out. The Registrant is accordingly requested to carry out a risk characterisation for the physicochemical properties of the substance, and update the CSR for this endpoint.

3) Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 15 months from the date of adoption of the decision.
ECHA has amended the time given for submission of the information required in the form of an updated IUCLID dossier, providing 18 months for the information in 1a and 2a-d, and providing 48 months for the information in 1b and 1c to take into account the time needed to perform the carcinogenicity study.

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 ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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.

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]

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Executive Director