

Decision number: CCH-D-0000001959-58-03/F

Helsinki, 30 March 2012

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

**For [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide, CAS No 25155-25-3 (EC No 246-678-3), 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 [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide, CAS No 25155-25-3 (EC No 246-678-3), submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1000 tonnes or more per year.

The compliance check was initiated on 25 July 2011.

On 14 September 2011 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 14 October 2011 and 20 October 2011 ECHA received comments from the Registrant agreeing to the draft decision.

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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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.

II. Information required

- 1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

- a. Name, molecular and structural formula (Annex VI, 2.1. and 2.2.). The Registrant shall provide sufficient information on the reference substance to enable the substance identity to be determined;
- b. The composition of the substance (Annex VI, 2.3). The information on the concentration ranges shall be representative of the registered substance as manufactured, and shall not encompass compositions corresponding to other substances;
- c. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.). The information shall be sufficient for each method to be reproduced, and shall therefore include details of the experimental protocol followed, the calculation used and the results obtained;
- d. The nature of impurities, as well as the percentage of (significant) main impurities (Annex VI, 2.3.2. and 2.3.3.).

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 **29/05/2012**.

### 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 greater than 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and with Annex VI 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 substance identity

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

The composition of the substance corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

- (a) The name, structural formula, the SMILES notation and InChI code indicated in the IUCLID dossier chapters 1.1 and 1.2 do not align with the submitted spectral information. The analytical data provided show that the substance is a multi-constituent substance composed of two isomers, 1,3-bis[2-(tertbutylperoxy)propan-2-yl]benzene and 1,4-bis[2-(tert-butylperoxy)propane-2-yl]benzene, whereas the structural formula, SMILES notation and InChI code refer to only one isomer.

Therefore the Registrant is requested to submit the correct structural formula and SMILES notation for the registered substance in accordance with Annex VI, section 2.2.1 of the REACH Regulation ensuring that the information is consistent throughout the dossier. In addition, the Registrant is requested to revise the IUPAC name to "Reaction mass of 1,3-bis[2-(tertbutylperoxy)propan-2-yl]benzene and 1,4-bis[2-(tert-butylperoxy)propane-2-yl]benzene" and include the CAS name, Peroxide, 1,1'-[1,3(or

1,4)-phenylenebis(1-methylethylidene)]bis[2-(1,1d-dimethylethyl) in the IUCLID dossier.

- (b) According to section 1.2 of the IUCLID dossier, the registered substance is composed of two isomers: [1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide and di-tert-butyl  $\alpha,\alpha,\alpha',\alpha'$ -tetramethyl-(p-phenylenedimethylene) diperoxide. The concentration range of each constituent as indicated in the dossier is from 0% to 100% w/w. This concentration range for a multi-constituent substance is excessively wide resulting in the impossibility to establish the specific identity of this substance. This composition can cover more than one substance, including the registered multi-constituent substance with EC name [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide, with EC No 246-678-3, as well as two mono-constituent substances: the substance with EC name 1,3-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide and EC No 218-664-7, and the substance with EC name  $\alpha,\alpha,\alpha',\alpha'$ -tetramethyl-(p-phenylenedimethylene) diperoxide and EC No 220-479-1. Therefore the Registrant is requested to revise the specified concentration ranges of the two main constituents of the registered multi-constituent substance, in accordance with Annex VI, section 2.3. of the REACH Regulation. As a general rule in the ECHA guidance, a multi-constituent substance is a substance defined by its composition in which more than one main constituent is present in a concentration  $\geq 10\%$  (w/w) and  $< 80\%$  (w/w). The Registrant is reminded that a separate registration shall be submitted for the mono-constituent substances, if the Registrant indeed manufactures or imports these.
- (c) The registration did not contain sufficient details of analytical methods to determine the main constituent and the impurity which is required by Annex VI, section 2.3.7. of the REACH Regulation. A sufficient description of the method used to quantify the main constituents and the impurities was not given. The Registrant has not provided a peak table with peak area and corresponding concentrations, and also details on the calibration/calculations used. The peak allocation is also not clear. Therefore, the Registrant is requested to submit all the missing information in accordance with Annex VI, section 2.3.7. of the REACH Regulation.
- (d) A number of constituents, including at least 14 impurities, in addition to the two main constituents, have been identified in the attached gas chromatogram (GC), but not included in section 1.2 of the IUCLID dossier. All impurities at a concentration in the substance at  $\geq 1\%$ , are required to be identified and quantified. This also applies to impurities if they contribute to the classification and/or PBT assessment of the substance irrespective of their concentration in the substance. Therefore the Registrant is requested to create a reference substance for each known impurity, indicating the typical, maximum and minimum concentration. The assigned reference substance should include as a minimum the following set of information: EC number (if available), CAS information (if available), IUPAC name, molecular formula and structural formula. The reference substance "unknown impurities" created by the Registrant in section 1.2 should be used when it is not technically possible to identify one or more impurities. In such a case, in the remarks field the number of unknown impurities should be indicated.

IV. 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](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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