EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000001967-61-03/F Helsinki, 27 February 2012

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

For 2-Butanone, peroxide, CAS No 1338-23-4 (EC No 215-661-2), 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 2-Butanone, peroxide, CAS No 1338-23-4 (EC No 215-661-2) submitted by [redacted] (Registrant), latest submission number [redacted], for over 1000 tonnes per year.

The compliance check was initiated on 7 September 2011.

On 14 September 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 13 October 2011 the Registrant provided to ECHA comments on the draft decision.

ECHA reviewed the further information received and amended the draft decision accordingly.

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 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 is targeted on substance identity and does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

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. The name or other identifiers for the substance (Annex VI, 2.1.) and the molecular and structural formula including, if available, SMILES notation (Annex VI. 2.2.1.). The Registrant shall provide sufficient and consistent information on the reference substance to enable the substance identity to be determined;
b. The composition of the substance (Annex VI, 2.3.). The Registrant shall provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under point III.(b) below;
c. The nature and order of magnitude of any additives (Annex VI, 2.3.4.). The Registrant shall indicate only the solvents and stabilizers which are necessary and only indicate the upper limit concentrations which are minimally necessary to guarantee the stability of the substance;
d. 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.

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 **27 April 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 >1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and Annex VI thereof. Consequently, the Registrant is requested to submit the information related to substance identity mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

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.

(a) The provided name of the substance cannot be confirmed and verified as the information provided in the registration dossier is not consistent. The substance is identified as mono-constituent substance with the generic EINECS entry, 2-Butanone, peroxide with the EINECS number 215-661-2 and CAS number 1338-23-4 which would suggest that the substance is rather a UVCB substance. However, the provided molecular and structural formula and the SMILES notation refer to another substance for which the indicated EINECS entry does not match. In fact, this structural information refers to the EINECS entry with the EC number 204-802-3 and EC name dioxybis(1-methylpropylidene) hydroperoxide with the CAS number 126-76-1. The Registrant shall

clarify the identity the substance by allocating a substance name which is in accordance with the principles of the guidance for identification and naming of substances under REACH. Furthermore the Registrant has to clarify and correct the mismatch of substance name, SMILES notation, molecular and structural formula.

(b) The indicated composition of the substance requires clarification. The substance is registered as a mono-constituent substance with the justification "Total active oxygen must be [redacted]. Different additives acting as stabilizing agents cannot be totally separated due to explosive properties of the substance. Thus, 2-Butanone, peroxide (upper limit [redacted]) is regarded as mono-constituent substance". However, the information provided on the chromatography, NMR spectra and quantitative composition of the material suggests that the substance contains several peroxide constituents which are not listed separately in section 1.2 of the IUCLID file. Two peroxide constituents are identified as dioxybis(1-methylpropylidene) hydroperoxide and sec-butylidene hydroperoxide which refer to the EINECS entries with the EINECS number 204-802-3 and the CAS number 126-76-1 and the EINECS number 220-091-2 and CAS number 2625-67-4 respectively. It is unclear form the provided analytical information whether or not other peroxide constituents are present in the substance. In addition no information on the individual contents of the two identified peroxide constituents is provided with the consequence that the qualitative and quantitative composition of the substance remains unclear. The Registrant shall clarify the composition of the substance and align the information provided in the dossier.

(c) The registered substance contains a high content of solvents and stabilizers which is not justified with the concentration ranges indicated. The registered substance refers to the substance group of peroxides which are known as unstable and explosive. Therefore, solvents cannot be fully removed due to decomposition caused by heat and additives are necessary to stabilize the explosive substance for safe handling and use. However, the substance contains these solvents and stabilizers in concentrations which are not justified and not necessary to guarantee its stability and safe use. [redacted] is indicated as solvent and stabilizer with a concentration range of [redacted] and with a typical concentration of [redacted]. The typical concentration indicates that [redacted] is not necessary for the stability of the substance and it should be removed from the substance composition. Finally, the content of the main stabilizer [redacted] is given with a concentration range of [redacted] and a typical concentration of [redacted]. The typical concentration indicates that the stabilizer does not need to be present in high concentration. Therefore, the upper concentration limit of [redacted] should not be used. Furthermore, it is indicated in the additive/solvent statement attached to section 13 that "...MEKP is therefore commercially produced and available only in combination with stabilizers such as [redacted], [redacted] and [redacted]. The available products contain one, two or all three of the aforementioned solvents. The solvents cannot be totally separated due to explosive properties of the substance...." Therefore, it is unclear which solvent is actually used and in which concentration necessary to stabilise the substance. Hence, the Registrant shall update the registration dossier and indicate only the solvents and stabilizers which are necessary in the upper limit concentrations which are minimally necessary to guarantee the stability of the substance.

(d) The description of the analytical methods is essential to derive the exact composition of the registered substance. The provided information on the analytical methods applied is

not sufficient to reproduce the methods. The content of the peroxide constituent(s) and hydrogen peroxide could not be analyzed by chromatographic methods. It is only indicated in the substance characterization report that "For the content of hydrogen peroxide (H_2O_2) and the different MEKP species a certain extraction procedure exists to separate the different compounds after this the content is determined via a common iodometric titration. The content of water was measured via coulometric Karl-Fischer analysis. For the stabilizer [redacted], the content is given from the mass balance of the production process (see attached flow-chart)." The extraction procedure for the peroxide constituents is not further specified and no detailed information on the iodometric titration is given therefore, the quantification of the individual peroxide constituents cannot be followed and reproduced. Moreover, the stabilizer and solvents are stable and do not decompose therefore, an appropriate analytical method has to be applied for the quantification of these constituents. The Registrant shall provide information on the analytical methods for all constituents present in the substance in such detail that these methods can be reproduced.

Furthermore, the Registrant requested an extension of the deadline for further two months in order to provide the analytical measurements identifying the different components, impurities and stabilizers. ECHA understands that providing a reliable quantification data for the different MEKP species (monomer and dimer) is quite challenging. However, ECHA believes that the deadline provided to the Registrant (i.e. 2 months from the date of the final decision) is sufficient to provide all the information requested under Section II a-d. In particular ECHA believes that the analytical requirements for the determination of the different components, impurities and stabilizers could be fulfilled and provided by the Registrant within the requested deadline since a procedure to separate and quantify the different constituents already exists.

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. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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