EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292043-55-01/F Helsinki, 9 February 2015

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

For α,α-dimethylbenzyl hydroperoxide, CAS No 80-15-9 (EC No. 201-254-7) 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 for **α,α-dimethylbenzyl hydroperoxide, CAS No 80-15-9 (EC No. 201-254-7)**, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Section 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band between 100 and 1000 tonnes and above per year. This decision does not take into account any updates submitted after 30 October 2014, 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 present registration at a later stage.

The compliance check was initiated on 14 May 2014.

On 14 July 2014 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 28 August 2014 ECHA received comments from the Registrant on the draft decision. ECHA considered the Registrant's comments. On basis of the comments, Section II (Information required) was not amended but the Registrant's comments are reflected in the Statement of Reasons (Section III).

On 30 October 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(d), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

- Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **16 February 2016**.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement.

- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

A "Pre-natal developmental toxicity study" is an information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has proposed to adapt the information requirement of Annex IX, Section 8.7.3. The Registrant has made a reference to corrosivity of the registered substance.

According to the fourth introductory paragraph of Annex IX of the REACH Regulation "*in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". However, ECHA would like to point out that non-corrosive concentration(s) can be tested. The fourth introductory paragraph of REACH Annex IX is not a legal basis for adapting standard information requirements. Moreover, ECHA would emphasise that the introductory paragraph refers to corrosive concentrations, not to corrosivity as such, and that corrosive substance can be diluted and the concentration decreased. Consequently, corrosion of the tissue of the test animals would not take place.

Therefore, recognising that the registered substance is classified as corrosive, the Registrant is advised to examine how the concentration of the test substance can be adjusted to avoid corrosion while at the same time allowing detection of potential systemic toxicity effects of the substance.

Since the fourth introductory paragraph of Annex IX is not a legal basis for adapting the standard information requirement, the adaptation suggested by the Registrant cannot be accepted.

Furthermore, the Registrant claims that the DNEL derived from a sub-chronic toxicity study made using the inhalation route, will prevent from the possible developmental toxicity effects of the substance.

ECHA points out that Column 2 of Section 8.7. of Annexe IX of the REACH Regulation does not include the possibility of adapting the information requirement based on DNEL obtained from a repeated dose toxicity study, in order to fulfil the requirement of a pre-natal developmental toxicity study.

The Registrant has also referred to exposure considerations. However, the Registrant has not claimed nor demonstrated with adequate and reliable documentation that any of the criteria given in Annex XI, Section 3.2., which concerns exposure based adaptations, would be met.

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Registrant has pointed out in his comment that oral route may not be most appropriate, since the substance will hydrolyse in stomach. ECHA considers that hydrolysis as such does not make the oral route less appropriate than other routes, in particular if the half-life is 53 hours at pH 1.2, as stated by the Registrant.

ECHA recognises that the second point raised by the Registrant, i.e. the narrow window between no effect (including reproductive functions) and lethal effects, appears to affect or complicate testing via any route of exposure.

Concerning the inhalation route ECHA notes that

- the vapour pressure of the substance is low, 0.0044 hPa,
- industrial and non-industrial spraying application have been specified in the process and use categories in the Chemical Safety Report, the Registrant claims that the use and handling mostly takes place under Strictly Controlled Conditions (SCC), which suggest that even in spraying applications, the exposure remains non-significant or low, and
- oral route is the default according to the OECD TG 414.

In conclusion, recognising that there may be some difficulties associated to the oral route as pointed out by the Registrant, ECHA does not agree that inhalation route should be preferred in this case, and requests the Registrant to carry out the test using oral administration. The Registrant is furthermore advised to design the study carefully in order to observe potential health effects while considering the available information of the NOAEL and corrosive level/concentration of the substance.

Furthermore, in his comment the Registrant justifies the waiving of this test by the lack of effects in the Dominant lethal assay. However, ECHA notes that the Dominant lethal assay is a genotoxicity test, in which only male animals are treated with the test substance. Therefore, the test is not appropriate to detect teratogenic effects caused by exposure of gravid females to the test substance, as the females are not exposed to the test substance. In this type of assay, malformations, individual anomalies and other relevant alterations in foetus cannot be covered.

Moreover, the fact that two hydrolysis products (phenol and acetone) are not classified for reproduction toxicity and developmental effects is not a sufficient justification for not to perform the study requested.

In conclusion, neither any of the adaptations alone nor when they are taken together, can be used to cover the relevant information requirement.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to submit information on Pre-natal developmental toxicity on rats or rabbits (test method EU B.31/OECD 414) on the registered substance.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally 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.

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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Leena Ylä-Mononen
Director of Evaluation