27.01.2010
CLH-0-0000000791-75-03/F

Opinion of the Committee for Risk Assessment on a dossier proposing harmonised Classification and Labelling at Community level

In accordance with Article 37 (4) of the Regulation (EC) No 1272/2008 ("the CLP Regulation"), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name: ***Di-tert-butyl peroxide (DTBP)***

EC Number: ***203-733-6***

CAS Number: ***110-05-4***

The proposal was submitted by ***France***
and received by ECHA on ***02 June 2009***

PROCESS FOR ADOPTION OF THE OPINION

France has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at http://echa.europa.eu/doc/consultations/cl/clh_axrep_france_di_tert_butyl_peroxide.pdf on ***12 June 2009***. MSCAs and parties concerned were invited to submit comments and contributions by ***27 July 2009***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Annemarie Losert***
Co-rapporteur, appointed by RAC: ***Andrew Smith***

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37 (4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on ***27 January 2010,*** in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex II.

The RAC Opinion was adopted by ***consensus.***

OPINION OF RAC

The RAC adopted the opinion that ***Di-tert-butyl peroxide*** should be classified and labelled as follows[1]:

Classification & labelling in accordance with Directive 67/548/EEC

Classification: O; R7, F; R11, Muta. Cat. 3, R68

Specific concentration limits: None

Notes: None

Labelling: O; F; Xn; R: 7-11-68…S(2-)3/7-14-16-23-36/37/39

Classification & Labelling in accordance with the Classification, Labelling and Packaging Regulation:

Classification: Org. Perox. E –H242, Flam. Liq. 2 – H225, Muta. 2 – H341

Specific concentration limits: None

M-factors: None

Notes: None

Labelling: Danger GHS 02 GHS 08 – H242, H225, H341

OPINION ON JUSTIFICATION FOR NEED FOR ACTION AT COMMUNITY LEVEL

Not appropriate given that this opinion relates to the addition of a mutagenicity classification only.

SCIENTIFIC GROUNDS FOR THE OPINION

The opinion relates only to those hazard classes that have been reviewed in the proposal for harmonised classification and labelling, as submitted by France.

Germ Cell Mutagenicity

As described in the dossier submitted originally by France and the BD prepared by RAC, di-tert-butyl peroxide has been found to give negative results for mutagenicity *in vitro* in bacteria. However, its potential to damage chromosomes or induce gene mutations in mammalian cells *in vitro* has not been studied. In two well conducted mouse bone marrow micronucleus tests, di-tert-butyl peroxide has given clear positive results. These mutagenic effects in somatic cells *in vivo* justify the classification of di-tert-butyl peroxide as category 3 mutagen, based on criteria in Directive 67/548/EEC (category 2 mutagen based on criteria in Regulation (No.) 1272/2008).

[1] Note that all hazard classes have not been evaluated

There are no grounds to classify di-tert-butyl peroxide any more stringently. No evidence is available to show that it can reach the germ cells, following relevant physiological exposure routes, and the only available germ cell test (for chromosome aberrations in spermatogonial cells of i.p. treated mice) was negative.

No additional data were provided during the public consultation; the received comments and the responses from the dossier submitter have been discussed and considered in the preparation of this opinion.

In summary, in relation with the criteria for germ cell mutagenicity:

- There are no human data and, therefore, classification as a Cat.1 Mutagen based on criteria in Directive 67/548/EEC (Cat.1A Mutagen based on criteria in Regulation (No) 1272/2008) is not appropriate
- *In vivo* data: In two well conducted mouse bone marrow micronucleus tests, di-tert-butyl peroxide has given clear positive results. These mutagenic effects in somatic cells *in vivo* justify the classification of di-tert-butyl peroxide as Cat. 3 Mutagen, based on criteria in Directive 67/548/EEC (category 2 mutagen, based on criteria in Regulation (No.) 1272/2008).
- There are no grounds to classify di-tert-butyl peroxide any more stringently. No evidence is available to show that it can reach the germ cells, following relevant physiological exposure routes, and the only available germ cell test (for chromosome aberrations in spermatogonial cells of intraperitoneally-dosed mice) was negative.

The Background Document, attached as Annex 1, gives the detailed scientific grounds for the Opinion.

ANNEXES:

Annex 1 Background Document (BD)[2]

Annex 2 Comments received on the CLH report and response to comments provided by the dossier submitter (excl. confidential information)

[2] The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter. The original CLH report may need to be changed as a result of the comments and contributions received during the public consultation(s) and the comments by and discussions in the Committees.