

27 January 2010
CLH-0-0000000794-69-03/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: *Trixylyl phosphate*
EC Number: *246-677-8*
CAS Number: *25155-23-1*

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

PROCESS FOR ADOPTION OF THE OPINION

The Netherlands 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_netherlands_trixylyl_phosphate.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: *Eugenio Vilanova*
Co-rapporteur, appointed by RAC: *Alicja Andersson*

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 *Trixylyl phosphate (TXP)* should be classified and labelled as follows¹:

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

Classification: Repr.Cat.2; R60

Specific concentration limits: None

Notes: None

Labelling: T; R60; S: 53-45

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

Classification: Repr. 1B; H360F

Specific concentration limits: None

M-factors: None

Notes: None

Labelling: GHS08, Danger; H360F²

Opinion on justification for need for action at Community level

Not needed for this hazard class.

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 the Netherlands.

Reproductive toxicity

RAC agrees with the proposal submitted by the Netherlands to classify TXP for reproductive toxicity as stated above.

The results of the available combined study on repeated dose toxicity and reproduction/developmental toxicity show a clear reduction on fertility with supporting evidence on the site of action, namely a significant and dose-related weight changes in testes,

¹ Note that all hazard classes have not been evaluated

² It is the view of RAC that hazard statement H360F is the most appropriate, given the available toxicological profile of trixylyl phosphate, but RAC recognised that H360 could be applied if the available criteria are applied strictly.

epididymides and ovaries, accompanied by histological changes in these organs. These effects are considered as an adverse effect on fertility, based on strong reduction of implantations in the middle and high dose combined with effects on the reproductive organs. In addition, at those dose levels only limited general toxicity was observed. The limited general toxicity was manifested as significant changes in clinical chemistry and partly reversible changes in organ weight, but these effects were considered as not severe.

Affected organs and the observed effects are similar to those observed after exposure to the structural analogue tricresyl phosphate (TCP). TCP interferes with steroidogenic tissue, and with cholesterol storage, which could be a part of the mechanism even for TXP. This indicated mechanism cannot be disregarded as not-relevant for humans.

So, as there is clear evidence for effects on fertility in the available study with TXP and additional evidence from TXP analogues, the criteria for classification for reproductive toxicity (fertility) in Category 2 (in accordance with Directive 67/548/EEC) and Category 1B (in accordance with the CLP Regulation) are met.

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

ANNEXES:

- Annex 1 Background Document (BD)³
- Annex 2 Comments received on the CLH report and response to comments provided by the dossier submitter (excl. confidential information)

³ 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.