Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at Community level of

perestane

ECHA/RAC/CLH-O-0000001562-79-03/F

Adopted

14 September 2011

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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 (CLP Regulation), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name: ***perestane***

EC Number: ***432-790-1***

CAS Number: ***847871-03-8***

The proposal was submitted by ***UK***
and received by RAC on ***25 March 2011***.

Harmonised classification proposed by the dossier submitter

	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC
Current entry in Annex VI CLP Regulation	Muta. 2 H341 Skin Corr. 1B H314 Acute Tox. 4* H332 Acute Tox. 4* H312 Acute Tox. 4* H302	Muta. Cat. 3; R68 - C; R34 - Xn; R20/21/22
Current proposal for consideration by RAC as proposed by dossier submitter	Removal of Muta. 2 H341 and addition of STOT-SE 2 H371	Removal of Muta. Cat.3; R68 and addition of Xn; R68/20/21/22
Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter	Skin Corr. 1B H314 Acute Tox. 4* H332 Acute Tox. 4* H312 Acute Tox. 4* H302 STOT-SE 2 H371	C; R34 Xn; R20/21/22 Xn; R68/20/21/22

PROCESS FOR ADOPTION OF THE OPINION

UK 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/consultations/harmonised_cl/harmon_cl_prev_cons_en.asp*** on ***25 March 2011.*** Parties concerned and MSCAs were invited to submit comments and contributions by ***9 May 2011***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Norbert Rupprich***

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 ***14 September 2011,*** in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment.

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

OPINION OF RAC

The RAC adopted the opinion that ***perestane*** should be classified and labelled as follows:

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water [Perestane]	**432-790-1**	**N/A**	**Skin Corr. 1B** **Acute Tox. 4*** **Acute Tox. 4*** **Acute Tox. 4*** **STOT SE 2 (eye)**	**H314** **H332** **H312** **H302** **H371**	**GHS05** **GHS07** **GHS08** **Dgr**	**H314** **H332** **H312** **H302** **H371**	-	-	-

Classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water [Perestane]	**432-790-1**	**N/A**	**C; R34** **Xn; R20/21/22** **Xn; R68/20/21/22**	**C** **R: 20/21/22-68/20/21/22** **S: 1/2-26-28-36/37/39-45**	-	-

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 *UK*.

Background

The classification proposal for perestane only deals with the removal of the current mutagenicity classification and the addition of a classification for specific target organ toxicity (single exposure).

The current classification of perestane for skin corrosion and for acute toxicity is not the subject of this classification proposal.

Based on the methanol content of perestane (3% to 10%) the classification of perestane has to account for the classification of methanol (3% to 10%).

Before the 28th ATP methanol at concentration levels between 3% and 10% had to be classified with R20/21/22-40/20/21/22. The risk phrase 40 was allocated because of evidence of permanent visual loss in humans. With the 28th ATP the R40 for acute irreversible effects was replaced by the risk phrase 68, leading to the DSD classification R20/21/22-68/20/21/22 for methanol (between 3% and 10%). The corresponding CLP classification is: Acute Tox. 4*; H332, H312 and H302; STOT SE 2; H371.

With the 28th ATP the R40 started to be used to indicate "limited evidence of a carcinogenic effect".

Specific target organ toxicity (single exposure)

Proposal of the dossier submitter

The dossier submitter proposes to classify perestane for specific target organ toxicity (single exposure). The justification for this proposal is that perestane contains methanol in a concentration of 3% to 10%. Because at this concentration level methanol is classified with STOT SE 2; H371 respectively Xn; R68/20/21, perestane is to be classified accordingly.

Comments submitted by concerned parties

All available comments supported the proposed classification for specific target organ toxicity (single exposure).

Outcome of the RAC assessment

RAC checked and discussed the proposed classification for specific target organ toxicity (single exposure). There was no comment in RAC and by concerned parties questioning the proposed classification. For corresponding details of the classification proposal please refer to the background document.

Overall, RAC concluded to propose to classify perestane for specific target organ toxicity (CLP: STOT SE 2; H371 and DSD: Xn; R68/20/21/22).

Mutagenicity

Proposal of the dossier submitter

The dossier submitter proposes to remove the mutagenicity classification for perestane. The dossier submitter explains that perestane was mistakenly classified for mutagenicity; there was no scientific justification for this classification. The misclassification is related to the change of the wording of the R40 phrase from "possible evidence of irreversible effects" to "limited evidence of a carcinogenic effect" at the 28th ATP.

Additionally, the dossier submitter summarised and discussed the available mutagenicity data on perestane and concluded that there is no scientific evidence for a mutagenicity classification for perestane.

Comments submitted by concerned parties

There was no comment during public consultation that questioned the proposal to remove the mutagenicity classification for perestane. Available comments either generally supported the proposal or asked for some clarification concerning the process of misclassification and for some details of the mutagenicity data. These comments have been accounted for in the current version of the background document.

Outcome of the RAC assessment

RAC recognises that perestane was mistakenly classified as a mutagen; this misclassification was related to a change in the definition of the risk phrase 40 with the 28th ATP. RAC appreciates that the dossier submitter nevertheless summarised and discussed the available mutagenicity data. The background summary contains a valid summary, discussion and evaluation of the mutagenicity data. For details of this mutagenicity assessment please refer to this background document.

Finally, RAC agrees to the conclusion of the dossier submitter that the available *in vitro* and *in vivo* mutagenicity data for perestane do not give evidence for *in vivo* soma cell mutagenicity and do not meet the criteria for a mutagenicity classification. Thus RAC concluded to propose to remove the current classification for mutagenicity.

Additional information

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

ANNEXES:

Annex 1	Background Document (BD)[1]
Annex 2	Comments received on the CLH report, response to comments provided by the dossier submitter and rapporteurs' comments (excl. confidential information)

[1] 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.