

Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at Community level of
reaction mass of

2,4,4-trimethylpent-1-ene

and

2,4,4-trimethylpent-2-ene

ECHA/RAC/DOC No CLH-O-0000001744-73-01/F

Adopted

10 June 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: reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene

EC Number: 246-690-9

CAS Number: 25167-70-8

The proposal was submitted by *Germany* and received by RAC on *20 August 2010*

The proposed harmonised classification originally proposed by the dossier submitter:

	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC (criteria)
Current entry in Annex VI CLP Regulation	-	-
Proposal from dossier submitter for consideration by RAC	Flam. Liq. 2 - H225 Asp. Tox. 1 - H304 STOT SE 3 - H336 EUH019	F; R11 R19 Xn; R65 R67
Resulting harmonised classification (future entry in Annex VI CLP Regulation) as proposed by dossier submitter	Flam. Liq. 2 - H225 Asp. Tox. 1 - H304 STOT SE 3 - H336 EUH019	F; R11 R19 Xn; R65 R67

PROCESS FOR ADOPTION OF THE OPINION

Germany 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 **20 August 2010**. Parties concerned and MSCAs were invited to submit comments and contributions by **4 October 2010**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Poul Bo Larsen***

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 **10 June 2011**, in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

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

OPINION OF RAC

The RAC adopted the opinion that reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene should be classified and labelled as follows:

CLP Regulation (EC) No 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 statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene	246-690-9	25167-70-8	Flam. Liq. 2 Asp. Tox. 1 STOT SE 3	H225 H304 H336	GHS02 GHS07 GHS08 Dgr	H225 H304 H336			D

Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene	246-690-9	25167-70-8	F; R11 Xn; R65 R67	F; Xn R: 11-65-67 S: (2-)46		D

SCIENTIFIC GROUNDS FOR THE OPINION

The classification of 2,4,4-trimethylpentene has been agreed of the TC C&L in September 2009. All endpoints have been addressed within this C&L proposal, since 2,4,4-trimethylpentene was a priority substance in the existing chemicals program (EEC) 793/93. The toxicological information present in this report is the same as that considered by the TC C&L in 2007 because no further data or relevant information was submitted for 2,4,4-trimethylpentene thereafter. However, with respect to physical-chemical properties the classification for formation of explosive peroxides (SDS: R19; CLP: EUH019) has been proposed by the DS and is not a conclusion taken over from the TC C&L group.

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

From the public consultation four Member States Competent Authorities (CA) comments were received all supporting the flammability and human health classifications and three of the CAs furthermore supported the R19 / EUH019 classification, whereas one industry (IND) comment opposed this classification.

Flammability

2,4,4-trimethylpentene meets the classification criteria as highly flammable liquid: The flash point measured in a closed cup is -7 °C and with a boiling point at 101.4 – 103.6 °C.

Conclusion:

Classification based on Directive 67/548/EEC:

F, R11 “Highly flammable”

Classification based on Regulation (EC) No 1272/2008:

Flam. Liq. 2 - H225 “Highly flammable liquid and vapour”

Explosivity

2,4,4-trimethylpentene is a peroxidisable chemical because it contains an **allylic hydrogen (C=C-CH-)** and Bretherick¹ gives guidance and examples of specific compounds and structural types for identifying substances which form explosive peroxides.

Due to this classifying with R19/EUH019 was proposed by the dossier submitter.

RAC does not consider that this classification apply to the substance, as reference to the more general description in *Bretherick's Handbook of Reactive Chemical Hazards* and not specifically addressing trimethylpentene is not considered sufficient evidence. Also no other alkenes have been classified on Annex VI for this end-point. Although peroxide formation may occur the extent of this in order to form risk for explosion has not been described. From IND comments and safety data sheets (SDS) it is stated that decomposition and polymerisation may occur and that commercial trimethylpentene is supplied with an inhibitor (antioxidant).

¹ P. G. Urben (Ed.): *Bretherick's Handbook of Reactive Chemical Hazards*, 7th ed., Elsevier 2007.

Therefore RAC finds the use of Note D applicable.

Note D:

Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3.

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words "non-stabilised".

Aspiration toxicity hazard

2,4,4-trimethylpentene is a branched hydrocarbon. It is 5 carbons long with 8 carbons in total and has a kinematic viscosity lower than 20.5 mm²/s (CLP criteria) and 7 mm²/s (DSD criteria).

Conclusion: Based on human experience as well as physico-chemical properties it is concluded to classify 2,4,4-trimethylpentene as:

Aspiration hazard category 1 (Asp. Tox. 1) - H304 "May be fatal if swallowed and enters airways" according to the CLP Regulation and Xn; R65 "Harmful: may cause lung damage if swallowed" according to Directive 67/548/EEC.

Specific target organ toxicity – single exposure: narcotic effects

Wistar rats (weight 160-210 g) were exposed for four hours (whole body exposure) to six different mist concentrations ranging from 7.6 to 44.0 mg/l. The substance was a mixture of C8 olefins (approx. 75% 2,4,4-trimethylpentene-1 and approx. 15% 2,4,4-Trimethylpentene-2). Twenty male and twenty female rats were used in each group/concentration. Mortality was noted starting at concentrations of 21 – 25 mg/l and the LC₅₀ was 31.5 mg/l (6 870 ppm) for male rats and 30.0 mg/l (6 540 ppm) for female rats. Exposure (concentration 21.6 mg/l; 4 900 ppm) of ten male and ten female Wistar rats for four hours/day and on five consecutive days resulted in death in 3/10 males and 2/10 females. Animals died within 24 hours. Clinical signs in surviving animals consisted of convulsions, followed by sedation and respiratory distress (Bayer AG, 1972).

Data from structurally analogous substance:

2,2,4-trimethylpentane (CAS No 540-84-1) is classified as R67 (Vapours may cause drowsiness and dizziness). In a five day inhalation study with repeated exposure with 13.2 or 21.6 mg/l and a 14-day observation period, male and female Wistar rats exhibited sedation and impeded breathing among others (Bayer AG 1972).

Criteria for classification based on data from animal studies:

Classification for narcotic effects "STOT Single 3" (May cause drowsiness or dizziness) is warranted, if data from animal toxicity studies shows clear symptoms of central nervous system depression (Regulation (EC) No 1272/2008). No concentration limit has been set in the criteria.

R67 (Vapours may cause drowsiness and dizziness) is warranted, if data from animal inhalation toxicity studies shows clear symptoms of central nervous system depression at concentrations/exposure times not exceeding 20 mg/l/4h (Directive 67/548/EEC).

Conclusion: Results from the available animal study have shown that 2,4,4-trimethylpentene causes clear signs of CNS depression which requires classification as STOT SE 3 – H336 (May cause drowsiness or dizziness) according to the CLP Regulation and R67 according to Directive 67/548/EEC.

Additional information

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, response to comments provided by the dossier submitter and rapporteurs' comments (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.