Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the 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/A2

Adopted

10 June 2011

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

[ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.]

Substance name: Reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene
CAS number: 25167-70-8
EC number: 246-690-9

General comments

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/08/2010	France / Elodie Pasquier / MSCA	The recommendations agreed at the TC C&L regarding the classification of trimethylpentenes are supported in absence of any new study since the TC C&L discussions and in agreement with the classification proposed in the CLH report. It is however noted that classification for these endpoints is not considered as a priority under CLP. Besides, compared to the proposal submitted at the TC C&L an additional classification for EUH19 has been introduced in the current CLH dossier and we agree that classification EUH19 is justified based on data. A proposal N; R50-53 was also presented in a proposal submitted at ECB in May 2007 although this endpoint has not been discussed and concluded by the TC C&L. The rationale for including in the current proposal the additional classification EUH19 but not additional environmental classifications is unclear. It is noted that additional guidance from the Commission on what are relevant justifications for harmonisation of classification of hand-over substances would be helpful to clarify these points. Finally, considering the article 4(3) of CLP, the inclusion of	Thank you for the support. At the moment, no data of different self classification by industry are available. Hence, a harmonised classification according to Article 36 (3) CLP Regulation is not justified. After publication of the C&L Inventory the possibility of harmonised classification for environment will be reconsidered. Note H, page 6:	See comments on R19/EUH019 below.

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		note H is not considered necessary.	We agree to your statement. The text for note H is deleted. See the revised CLH-report.	
26/08/2010	Sweden / MSCA	In absence of any new data Sweden supports the agreement, on the proposed classification and labelling for Reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene, taken by the Technical Committee on Classification and Labelling (Directive 67/548/EEC) ('TC C&L').	Thank you for the support.	No further comments
29/09/2010	UK / MSCA	We recognise that this is a 'transition' substance for which the C&L was agreed by the TC C&L. As such, the comments submitted below are observations to ease the progress of 2,4,4-trimethylpentene through the new CLP harmonised classification and labelling system.	Thank you for the support.	No further comments
30/09/2010	Ireland / MSCA	The Irish CA supports the classification for reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene as previously agreed by TC C&L. We are also in agreement with translated classification under CLP of Flam. Liq. 2, Asp. Tox. 1 and STOT SE 3.	Thank you for the support.	No further comments

Carcinogenicity

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Mutagenicity

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Toxicity to reproduction

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Respiratory sensitisation

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment

Other hazards and endpoints

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
29/09/2010	UK / MSCA	Page 11. Aspiration toxicity hazard. We would support the proposed classification as Asp. Tox. 1 – H304 / Xn; R65 but would appreciate clarification over the statement from the RAR that is included as the main basis of the proposal. 2,4,4-Trimethylpentene is 5 carbons long with 8 carbons in total. Does the aspiration hazard relate to branched substances? Page 13. Single target organ toxicity. We support the proposal for STOT-SE 3 – H336/ Xn; R67. Page 15. Physico-chemical properties. We agree with the proposal to classify the substance with Flam. Liq. 2; H225 and EUH019 (F;R11 and R19).	Aspiration toxicity hazard, now page 12ff: Thank you for the support. The text was amended. See the revised CLH-report. There are a lot of branched substances in Annex VI to Regulation (EC) No 1272/2008 classified as Asp. Tox. 1-H304 / Xn; R65, summarized under index number, e.g.: 601-007-00-7; 601-008-00-2; 601-009-00-8 (http://ecb.jrc.ec.europa.eu/classification-labelling/clp/). Thank you for the support.	See comments on R19/EUH019 below.

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
30/09/2010	Ireland / MSCA	The classification agreed by the TC C&L did not appear to include a proposal for R19. However, based on the justification provided in the Annex VI report, and on the basis of providing supplemental hazard information, we can agree to the addition of R19/ EUH019.		See comments on R19/EUH019 below.
04/10/2010	Belgium / Lower Olefins and Aromatics Reach Consortium / Industry or trade association	*ECHA comment: The comment below was sent as an attachment (2010 10 04 Response to Proposal to Label Trimethylpentene with R19.doc).* **Response to Proposal to Label Trimethylpentene with R19 (May form explosive peroxides)** The following information is given following the experience of the European manufacturers of 2,4,4-trimethylpentene and also the considerable work done when creating the REACH registration dossier for this substance Summary Labelling olefins like 2,4,4-trimethylpentene with R19 (May form explosive peroxides) or EU H019 is not justified. Rationale • The Directive 67/548 and the CLP-Regulation both give the following criteria for labelling: "For substances and mixtures which may form explosive peroxides during storage, such as diethyl ether,1,4-dioxane" Whilst olefins may in principle form peroxide in presence of oxygen the potential is not nearly as high as those for ethers. • Although peroxides may slowly form under normal storage conditions, the reaction is slow and it is extremely unlikely that peroxides would accumulate to a level that would pose a	The rejection of the proposal to label Trimethylpentene with R19 by Lower Olefins and Aromatics Reach Consortium / Industry is inconsistent. On the one hand they argue that peroxides may slowly form under normal storage conditions, the reaction is slow and it is extremely unlikely that peroxides would accumulate to a level that would pose a risk of explosion and otherwise the product is delivered with an antioxidant to avoid any oxidation processes and is delivered with a typical specification limit for peroxides which represents no risk. Shell Chemicals Europe B.V. give information on the stability of Diisobutylene in Section 10 of the Material Safety Data Sheet (Version 1.6; 07.08.2008) "Oxidises on contact with air to form unstable peroxides." Furthermore, there is no	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

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		risk of explosion. •Literature search on the oxidation of 2,2,4-trimethylpentenes (DIB) has been performed and no references to hydroperoxide formation have been found. •There is no evidence of peroxide or peroxide decomposition products (alcohols or ketones) in commercial samples that have been analysed in the recent past. • Commercial 2,4,4-trimethylpentene is supplied with an inhibitor is delivered with a typical specification limit for peroxides which represents no risk. • It is noted that in EU- CLP- regulation 1272/2008 only ethers are classified with EUH019 but not olefins although many are given in the associated tables. Other similar olefins with allylic hydrogens do not have R19 phrases. • 2,4,4-trimethylpentene does not have a practically reactive double bond as compared to other short chain olefins. • The product is delivered with a typical specification limit for peroxides which represents no risk. Furthermore the product is delivered with an antioxidant to avoid any oxidation processes. • 2,4,4-Trimethylpentene is classified as a highly flammable liquid with labelling P233: Keep container tightly closed This would also be the appropriate risk management measure control measure to avoid peroxide formation during	description in the SDS of any stabilisers, which are used to maintain the chemical stability of the mixture. Additional in the confidential Appendix I of the CLH-Report on the composition and the impurities of the substance, there has been listed neither an inhibitor nor an antioxidant. The Industry's interpretation on labelling requirement for R19/EUH019 "May form explosive peroxides" that this applies only to ethers is wrong. According to the classification principles set out in Directive 67/548/EEC - Annex VI, as well as Regulation (EC) No 1272/2008, Annex II, 1.1.5, the statement R19 / EUH019 should be applied for substances and mixtures which may form explosive peroxides during storage, such as diethyl ether, 1,4-dioxan. For a long time (30 years) diethyl ether and 1,4-dioxane are mentioned in the Directive 67/548/EEC because they are the most common solvents, which are used in the	with an inhibitor (antioxidant). 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

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		storage – as it excludes oxygen. It is concluded that 2,4,4-trimethylpentene does not require labelling as R19/ H019.	laboratory. Solvents containing ether, acetal, isopropyl, allyl, vinyl or diene groups and bearing a susceptible hydrogen atom, can form unstable peroxides on exposure to light and air. Bretherick [1] gives guidance and examples of specific compounds and structural types for identifying substances which form explosive peroxides. In our opinion the labelling of Trimethylpentene with R19/EUH019 is justified. [1] P. G. Urben (Ed.): Bretherick's Handbook of Reactive Chemical Hazards, 7th ed., Elsevier 2007. SDS:  Adobe Acrobat Document	by the words "non-stabilised".

LIST OF ORIGINAL DOCUMENTS RECEIVED AS COMMENTS

From industry: Safety Data Sheet (Shell Chemicals Europe B.V., information on the stability of Diisobutylene in Section 10 of the Material Safety Data Sheet (Version 1.6; 07.08.2008))