

Annex VI Report

PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

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

Submitted by: Germany

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PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

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

Registration number (s):

Purity: minimum $\geq 90\%$

Proposed classification based on Directive 67/548/EEC criteria:

F; R11	Highly flammable
R19	May form explosive peroxides.
Xn; R65	Harmful: may cause lung damage if swallowed
R67	Vapours may cause drowsiness and dizziness

(Note: A harmonisation of the classification for the environmental hazards is not proposed in this dossier.)

Proposed classification based on GHS criteria:

Flam. Liq. 2; H225	Highly flammable liquid and vapour
Asp. Tox. 1; H304	May be fatal if swallowed and enters airways
STOT–SE 3; H336	May cause drowsiness or dizziness
EUH019	May form explosive peroxides.

(Note: A harmonisation of the classification for the environmental hazards is not proposed in this dossier.)

Proposed labelling:

F; Xn

R: 11-19-65-67

S: (2-9-)16-29-60-62

Proposed specific concentration limits (if any):

Proposed notes (if any):

The proposed harmonised classification applies only to selected hazardous properties. So we propose to use “Note H” in Annex VI of the CLP-Regulation.

Note H (Table 3.1):

The classification and labelling shown for this substance applies to the hazardous property(ies) indicated by the hazard statement(s) in combination with the hazard class(es) and category(ies) shown. The requirements of Article 4 for manufacturers, importers or downstream users of this substance apply to all other hazard classes and categories. For hazard classes where the route of exposure or the nature of the effects leads to a differentiation of the classification of the hazard class, the manufacturer, importer or downstream user is required to consider the routes of exposure or the nature of the effects not already considered. The final label shall follow the requirements of Article 17 and of section 1.2 of Annex I.

Note H (Table 3.2):

The classification and label shown for this substance applies to the dangerous property(ies) indicated by the risk phrase(s) in combination with the category(ies) of danger shown. Manufacturers, importers and downstream users of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of section 7 of Annex VI to Directive 67/548/EEC.

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

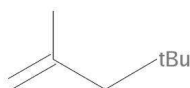
1.1 Name and other identifiers of the substance

Chemical Name: Pentene, 2,4,4-trimethyl-
EC Name: 2,4,4-trimethylpentene
CAS Number: 25167-70-8
IUPAC Name: reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene

1.2 Composition of the substance

For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.

Chemical Name: 2,4,4-trimethylpent-1-ene
EC Number: 203-486-4
CAS Number: 107-39-1
IUPAC Name: 2,4,4-trimethylpent-1-ene
Molecular Formula: C₈H₁₆
Structural Formula:



Molecular Weight: 112.2 g/mol
Typical concentration (% w/w): Confidential
Concentration range (% w/w): Confidential

Chemical Name: 2,4,4-trimethylpent-2-ene
EC Number: 203-488-5
CAS Number: 107-40-4
IUPAC Name: 2,4,4-trimethylpent-2-ene
Molecular Formula: C₈H₁₆

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Structural Formula:



Molecular Weight: 112.2 g/mol

Typical concentration (% w/w): Confidential

Concentration range (% w/w): Confidential

1.3 Physico-chemical properties

Table 1.1 Summary of physico- chemical properties

REACH ref Annex, §	Property	IUCLID section	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	colourless liquid at 20 °C, 10.13 kPa	RÖMPP Chemie Lexikon Online (2007)
VII, 7.2	Melting/freezing point	4.2	< -50 °C (freezing point)	Shell Research (1997)
VII, 7.3	Boiling point	4.3	101.4 – 103.6 °C at 1 013 hPa (method according to Siwoloboff)	Shell Research (1997)
VII, 7.4	Relative density	4.4 density	0.7166 at 20 °C (hydrometer method)	Shell Research (1997)
VII, 7.5	Vapour pressure	4.6	57.90 hPa at 25 °C (static method)	Shell Research (1996)
VII, 7.6	Surface tension	4.10	69.9 mN/m at 20 °C c: ca. 1.6 mg/l (ring method)	Shell Research (1997)
VII, 7.7	Water solubility	4.8	1.8 mg/l at 20 °C (flask method)	Shell Research (1997)
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7 partition coefficient	5.0 at 25 °C (HPLC-method)	Shell Research(1997)
VII, 7.9	Flash point	4.11	-7 °C (closed cup)	Expert judgement by PTB (1996)
VII, 7.10	Flammability	4.13	<p>Pyrophoric properties: The classification procedure need not to be applied because the organic substance is known to be stable into contact with air at room temperature for prolonged periods of time (days). Flammability in contact with water: The classification procedure need not to be applied because the organic substance does not contain metals or metalloids.</p> <p>Explosion limits in air: <i>Lower: 0,7 vol%</i> <i>Upper: 5,8 vol%</i></p>	<p>BAM II.2 (2010)</p> <p><i>SDS, Erdölchemie (10/93)</i></p>

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VII, 7.11	Explosive properties	4.14	The classification procedure need not to be applied because there are no chemical groups present in the molecule which are associated with explosive properties, but 2,4,4-Trimethylpentene may form unstable peroxides by auto-oxidation on contact with air. Due to this fact classifying with R19 is proposed.	BAM II.2 (2010) Reference: P. G. Urben (Ed.): <i>Bretherick's Handbook of Reactive Chemical Hazards</i> , 7th ed., Elsevier 2007.
VII, 7.12	Self-ignition temperature	4.12	380 °C (<i>DIN 51794</i>)	Expert judgement by PTB (1996)
VII, 7.13	Oxidising properties	4.15	The classification procedure need not to be applied because the organic substance does not contain oxygen, fluorine or chlorine.	<i>BAM II.2 (2010)</i>
VII, 7.14	Granulometry	4.5	---	---
XI, 7.15	Stability in organic solvents and identity of relevant degradation products	4.17	---	---
XI, 7.16	Dissociation constant	4.21	---	---
XI, 7.17,	Viscosity	4.22	---	---
	Reactivity towards container material	4.18	---	---
	Thermal stability	4.19	---	---
	Henry's law constant	4.23	$2.127 \cdot 10^5 \text{ Pa} \cdot \text{m}^3 \cdot \text{mol}^{-1}$	Lyman et al. (1982)

2 MANUFACTURE AND USES

2.1 Manufacture

2.2 Identified uses

2.3 Uses advised against

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

This should include the classification (including specific concentration limits) listed in Annex I of Directive 67/548/EEC (including the Index Number)

3.2 Self classification(s)

4 ENVIRONMENTAL FATE PROPERTIES

Not evaluated for this dossier.

5 HUMAN HEALTH HAZARD ASSESSMENT

Where appropriate, the proposed classification(s) should be included in the summary and discussions sections which will include weight of evidence considerations.

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

No data are available on 2,4,4-trimethylpentene.

Results from studies on structurally similar compounds:

Nose-only exposure of rats (300 g) to 2,3,4-trimethylpentane which represents a structurally similar but saturated compound resulted in a normalized uptake rate of 4-6 nmol/min per kg bw per ppm (exposure to 100 ppm, flow rate 400 ml/min for 80 min) (Dahl et al., 1988). The uptake rate refers to uptake during minutes 60 to 70 from start of exposure as determined by gas chromatographic measurements of inhaled and exhaled air. From these data it was calculated that approximately 7-

11% of the 2,3,4-trimethylpentane was retained and a value of 10% is proposed to be taken forward for risk characterisation purposes.

There are no studies available on oral or dermal absorption. From the physico-chemical data (log P 5.0, water solubility 1.8 mg/l, molecular weight 112 g/mol) the substance shows a good oral and dermal bioavailability. It is proposed to take forward for the risk characterisation a value of 100%.

In vitro studies on short chain olefins (n-1-octene, n-4-octene, and 3-ethyl-2-pentene) with rat liver microsomes demonstrated the conversion of olefins to diols via epoxide intermediates (Maynert et al., 1970). Similar reactions can be assumed for 2,4,4-trimethylpentene although the quantitative extent remains to be determined.

5.2 Acute toxicity

5.3 Irritation

5.4 Corrosivity

5.5 Sensitisation

5.6 Repeated dose toxicity

5.7 Mutagenicity

5.8 Carcinogenicity

5.9 Toxicity for reproduction

5.10 Other effects

5.10.1 Aspiration toxicity hazard:

In the draft RAR of 2007, the assessment was based on the following argumentation:

The assessment of the aspiration hazard posed by C6-C14 olefins is not based on EU classification criteria but on human experience summarised within a list of data compiled by the Shell Oil Company resulting in the statement: "Aspiration is a significant hazard with C6-C14 olefins". Similar considerations are mentioned in the Martindale Extra Pharmacopoeia published in 1982, stating on page 1452 for light petroleum: "Adverse Effects and Treatment. As for Kerosene, light petroleum and petrol, being more volatile than kerosene, are more likely to be inhaled and to cause aspiration pneumonitis. The toxicity of petrol varies with its composition". Hence, on the basis of the experience gained by producers of C8 olefins, we suggest that classification with R65 is warranted.

Criteria for classification

Aspiration toxicity hazard category 1 (Asp. Tox. 1) / R65 (Harmful: may cause lung damage if swallowed) / is also warranted for liquid substances and preparations because of their low viscosity.

Low viscosity leads to flow and low surface tension leads to spread of a liquid through the respiratory tract.

Aspiration toxicity hazard category 1 (Asp. Tox. 1) is also warranted, if the substance is a hydrocarbon and has a kinematic viscosity ν of 20.5 mm²/s or less, measured at 40°C (Regulation (EC) No 1272/2008, section 3.10.2).

R65 is warranted, if the substance is a hydrocarbon and has a kinematic viscosity ν of less than 7×10^{-6} m²/s (= 7 mm²/s) at 40°C (Directive 67/548/EEC).

While there is limited data on the viscosity of 2,4,4-trimethylpentene at different temperatures, the dynamic viscosity η of liquid organic compounds can be approximated on the basis of the De Guzman-Andrade equation (van Velzen et al. 1972):

$$\eta = 10^{B \cdot \left(\frac{1}{T} - \frac{1}{T_0} \right)} \quad [\text{mPa}\cdot\text{s}]$$

T is the Temperature, and T₀ and B are two calculable variables (see section 8.1.1 for more details):

Method 1: $\eta = 0.4183$ mPa·s

A second method is based on the normal boiling point, the number of hydrocarbons and the compound class (Grain 1990). The viscosity at the boiling point T_b is given (0.2 mPa·s), as well as a constant K_F relating to the structure. Another parameter n does not describe number of hydrocarbons but rather a tabulated value for the compound class (see section 8.1.2 for more details):

$$\eta = \eta_B \cdot e^{B_4 \cdot \left(\frac{1}{T} - \frac{1}{T_b} \right)} \quad [\text{mPa}\cdot\text{s}]$$

Method 2: $\eta = 0.0735$ mPa·s

The kinematic viscosity ν relates to the dynamic viscosity via the density ρ :

$$\nu = \frac{\eta}{\rho}$$

With density $\rho = 0.7166$ g·cm⁻³.

From Method 1 with a dynamic viscosity $\eta = 0.4183$ mPa·s, the kinematic viscosity of 2,4,4-trimethylpentene at 40°C is approximately 0.58 mm²/s, which is less than 20.5 mm²/s / 7 mm²/s, and requires labelling as proposed (see *Conclusion*).

From Method 2 with a dynamic viscosity $\eta = 0.0727$ mPa·s, the kinematic viscosity of 2,4,4-trimethylpentene at 40°C is approximately 0.10 mm²/s, which supports the other calculated value for kinematic viscosity, and requires labelling as proposed:

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

Aspiration toxicity category 1 (Asp. Tox. 1) H304 May be fatal if swallowed and enters airways

Xn; R65 Harmful: may cause lung damage if swallowed.

5.10.2 Single 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 LC 50 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

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

R67 (Vapours may cause drowsiness and dizziness) is warranted, if data from animal inhalation toxicity studies showing 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 labelling as STOT Single 3 (May cause drowsiness or dizziness).

With respect to Directive 67/548/EEC R67 (Vapours may cause drowsiness and dizziness) is proposed. Based on the above data from an animal study clear signs of CNS effects such as convulsions were evident at exposure concentration of 21.6 mg/l: Although little above the concentration limit of (20 mg/l/4h), this concentration is considered to be still in the range of upper limit concentration for classification.

It is proposed to classify 2,4,4-trimethylpentene as

Specific target organ toxicity – single exposure, category 3 (STOT–SE 3) H336 (May cause drowsiness or dizziness)

Xn; R67 (Vapours may cause drowsiness and dizziness).

5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

Not relevant for this type of dossier.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1 Explosivity

No experimental data on explosive properties:

Testing can be waived based on a consideration of the chemical structure in accordance with REACH Column 2 of Annex VII, section 7.11:

The classification procedure need not to be applied because there are no chemical groups present in the molecule which are associated with explosive properties.

No classification for explosivity is proposed.

2,4,4-Trimethylpentene is a peroxidisable chemical because it contains an *allylic hydrogen* (C=C-CH-) and Bretherick [1] gives guidance and examples of specific compounds and structural types for identifying substances which form explosive peroxides.

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

Due to this fact classifying with R19/EUH019 is proposed.

6.2 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.

Proposed classification based on Directive 67/548/EEC:

F, R11 Highly flammable

Proposed classification based on Regulation (EC) No 1272/2008:

Flam. Liq. 2; H225 Highly flammable liquid and vapour

6.3 Oxidising potential

No experimental data on oxidising properties:

Testing can be waived based on a consideration of the chemical structure in accordance with REACH Column 2 of Annex VII, section 7.13: The classification procedure need not to be applied because the organic substance does not contain oxygen, fluorine or chlorine.

No classification for oxidising properties is proposed.

7 ENVIRONMENTAL HAZARD ASSESSMENT

Not evaluated for this dossier.

JUSTIFICATION THAT ACTION IS REQUIRED ON A COMMUNITY-WIDE BASIS

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 proposal to classify with Xn; R65 (based on human data) and omit Xi; R37/38 was already submitted to TC C&L and was agreed on in September 2007. F; R11 and R67 (STOT SE 3, H336) were agreed on in follow-up I and II.

OTHER INFORMATION

It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g registration dossiers, other published sources) used for the dossier could also be indicated here.

8.1 Calculation of dynamic viscosity

8.1.1 Method 1 (van Velzen et al. 1972):

Aspiration toxicity hazard category 1 is also warranted, if the substance is a hydrocarbon and has a kinematic viscosity ν of 20.5 mm²/s or less, measured at 40°C (EC Regulation No 1272/2008, section 3.10.2). While there is limited data on the viscosity of 2,4,4-trimethylpentene at different temperatures, the dynamic viscosity η of liquid organic compounds can be approximated on the basis of the De Guzman-Andrade equation:

$$\log \eta = B \cdot \left(\frac{1}{T} - \frac{1}{T_0} \right)$$

$$\log \eta = B (1/T - 1/T_0)$$

equates to

$$\eta = 10^{B \cdot \left(\frac{1}{T} - \frac{1}{T_0} \right)} \quad [\text{mPa}\cdot\text{s}]$$

$$\eta = 10^{B (1/T - 1/T_0)} \quad [\text{mPa}\cdot\text{s}]$$

T is the Temperature [here: 40°C, 313.16K], and T₀ and B are two calculable variables (for n = number of carbon atoms ≤ 20; equations/ variables for ΔB₁, ΔB₂, ΔN₁, ΔN₂ and ΔN₃ are valid for alkenes with double *iso* configuration):

$$T_0 = 28.86 + 37.439 \text{ NE} - 1.3547 \text{ NE}^2 + 0.02076 \text{ NE}^3$$

$$B = B_a + \Delta B_1 + \Delta B_2$$

$$B_a = 24.79 + 66.885 \text{ NE} - 1.3173 \text{ NE}^2 - 0.00377 \text{ NE}^3$$

$$\Delta B_1 = -44.94 + 5.410 \text{ NE}$$

$$\Delta B_2 = 8.93$$

$$\text{NE} = n + \Delta N_1 + \Delta N_2 + \Delta N_3$$

$$\Delta N_1 = -0.152 - 0.042 n$$

$$\Delta N_2 = 1.389 - 0.238 n$$

$$\Delta N_3 = 0.93$$

$$n = 8$$

Results: NE = 7.927; B_a = 470.334; B = 477.209; T₀ = 250,854 K; η = 0.4183 mPa·s

8.1.2 Method 2 (Grain 1990):

This method is based on the normal boiling point T_b , the number of hydrocarbons and the compound class (Grain 1990). The viscosity at the boiling point T_b is given (0.2 mPa·s), as well as a constant K_F relating to the structure. Another parameter n does not describe number of hydrocarbons but rather a tabulated value for the compound class.

$$\eta_B = 0.2 \text{ mPa}\cdot\text{s} \quad (\text{table 22-3, Grain 1990})$$

$$K_F = 1.01 \quad (\text{table 14-4, Grain 1990})$$

$$n = 8 \quad (\text{table 22-5, Grain 1990})$$

$$T_b = 375,66\text{K} \quad (\text{mean, Shell Research 1997})$$

$$R = 1,987 \text{ cal}\cdot\text{mol}^{-1}\cdot\text{K}^{-1} \quad (\text{gas constant})$$

$$B_4 = \frac{1}{n} \cdot [K_F \cdot T_b \cdot (8.75 + R \cdot \ln T_b) - R \cdot T]$$

$$B_4 = 1/n [K_F T_b (8.75 + R \ln T_b) - RT]$$

$$\ln \eta = \ln \eta_B + B_4 \cdot \left(\frac{1}{T} - \frac{1}{T_b} \right)$$

$$\ln \eta = \ln \eta_B + B_4 (1/T - 1/T_b)$$

$$\eta = \eta_B \cdot e^{B_4 \left(\frac{1}{T} - \frac{1}{T_b} \right)} \quad [\text{mPa}\cdot\text{s}]$$

$$\eta = \eta_B \cdot e^{B_4 (1/T - 1/T_b)} \quad [\text{mPa}\cdot\text{s}]$$

Results: $B_4 = 886.270$, $\ln \eta = -1.1386$, $\eta = 0.0735 \text{ mPa}\cdot\text{s}$

$$1\text{cp} = 1\text{mPa}\cdot\text{s} = 0.01 \text{ g}\cdot\text{s}^{-1}\cdot\text{cm}^{-1}$$

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ANNEX