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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 02.08.2023 Version number 2 (replaces version 1) Revision: 02.08.2023

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

- · 1.1 Product identifier
 - · Trade name: PalaXtreme Liquid
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
 - · Application of the substance / the mixture Manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· Informing department: E-Mail: msds@kulzer-dental.com

· 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
 - Classification according to Regulation (EC) No 1272/2008

H225 Highly flammable liquid and vapour. Flam. Lig. 2

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. STOT SE 3

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms





GHS02 GHS07

- · Signal word Danger
- · Hazard-determining components of labelling:

methyl methacrylate

2-[[(butylamino)carbonyl]oxy]ethyl acrylate

(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. P261

P280 Wear protective gloves / eye protection.

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P280 Wear protective clothing.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· 2.3 Other hazards -

- Results of PBT and vPvB assessment
 - · PBT: Not applicable. · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

Description: -

· Dangerous components:		
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	75-90%
CAS: 63225-53-6 EINECS: 264-036-0 Reg.nr.: 01-2120751208-56- XXXX	2-[[(butylamino)carbonyl]oxy]ethyl acrylate Acute Tox. 3, H331 Aquatic Chronic 2, H411 Skin Sens. 1, H317	5-10%
CAS: 97553-94-1	Aliphatic urethane acrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319	0-5%
CAS: 40220-08-4 EINECS: 254-843-6 Reg.nr.: 01-2120741502-64-xxxx	(2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate Eye Dam. 1, H318 Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥1-<2.5%
CAS: 63393-96-4 EINECS: 264-120-7	Quaternary ammonium compounds, tri-C8-10- alkylmethyl, chlorides Acute Tox. 3, H301 Repr. 2, H361 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Chronic 1, H410 (M=1) ATE: LD50 oral: 200 mg/kg	≥0.025-<0.25%

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - After inhalation Supply fresh air; consult doctor in case of symptoms.
 - After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

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 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
 - · Suitable extinguishing agents CO2, sand, extinguishing powder. Do not use water.
 - For safety reasons unsuitable extinguishing agents Water.
- · 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
 - Protective equipment:

Wear self-contained breathing apparatus.

Wear full protective suit.

· Additional information -

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Prevent material from reaching sewage system, holes and cellars.
- 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Send for recovery or disposal in suitable containers.

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
 - · Storage
 - · Requirements to be met by storerooms and containers: Store in cool location.
 - Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions:
 - Store in cool, dry conditions in well sealed containers.
- · 7.3 Specific end use(s) No further relevant information available.

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8.1 Contro	ol parameters				
Components with critical values that require monitoring at the workplace:					
-	ethyl methacr		,	,	
WEL (Gre		Short-terr	m value: 416 mg n value: 208 mg	n/m³, 100 ppm n/m³ 50 ppm	
IOELV (European Union) Short-terr				m	
· DNI	ELs				
80-62-6 m	ethyl methacry	/late			
Oral	general popula	tion, long t	term, systemic	8.2 mg/Kg (not defined)	
Dermal	worker industri	al, long ter	rm, systemic	13.67 mg/Kg/d (not defined)	
	general popula	tion, long t	term, systemic	8.2 mg/Kg/d (not defined)	
Inhalative	worker industri	al, acute, l	local	416 mg/m3 (not defined)	
	worker industri	al, long ter	rm, systemic	348.4 mg/m3 (not defined)	
	worker industri	al, long ter	rm, local	208 mg/m3 (not defined)	
	general popula	tion, acute	e, local	208 mg/m3 (not defined)	
	general popula	tion, long t	term, systemic	74.3 mg/m3 (not defined)	
63225-53-	6 2-[[(butylami	ino)carboi	nyl]oxy]ethyl a	crylate	
Oral	general popula	tion, long t	term, systemic	1 mg/Kg (not defined)	
Dermal	worker industri	al, long ter	rm, systemic	2 mg/Kg/d (not defined)	
	general popula	tion, long t	term, systemic	1 mg/Kg/d (not defined)	
Inhalative	worker industri	al, long ter	rm, systemic	9.9 mg/m3 (not defined)	
	general popula			1.7 mg/m3 (not defined)	
				/l)triethylene triacrylate	
Oral	general popula	_	•	0.083 mg/Kg (not defined)	
Dermal	worker industri	-	•	2.3 mg/Kg/d (not defined)	
	general popula	_	•	0.83 mg/Kg/d (not defined)	
Inhalative	worker industri	-	•	1.65 mg/m3 (not defined)	
general population, long			0.29 mg/m3 (not defined)		
				tri-C8-10-alkylmethyl, chlorides	
	•	ional, long	term, systemic	0.42 mg/m3 (not defined)	
· PNI					
	ethyl methacry	ylate			
freshwater			0.94 mg/l (not defined)		
marine water		0.094 mg/l (not defined)			
sewage treatment plant		10 mg/l (not defined)			
sediment, dry weight, freshwater		10.2 mg/Kg (not defined)			
	dry weight, mai	ine water	0.102 mg/Kg (not defined)		
soil, dry w	-	. , .	1.48 mg/Kg (no		
		no)carboi	nyl]oxy]ethyl a		
freshwatei	r iter		0.003 mg/l (not 0 mg/l (not defii		



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sewage treatment plant	3.54 mg/l (not defined)
sediment, dry weight, freshwater	0.024 mg/Kg (not defined)
sediment, dry weight, marine water	0.002 mg/Kg (not defined)
soil, dry weight	0.003 mg/Kg (not defined)
40220-08-4 (2,4,6-trioxo-1,3,5-tria	zinane-1,3,5-triyl)triethylene triacrylate
freshwater	0.00943 mg/l (not defined)
marine water	0.000943 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.62 mg/Kg (not defined)
sediment, dry weight, marine water	0.062 mg/Kg (not defined)
soil, dry weight	0.118 mg/Kg (not defined)
63393-96-4 Quaternary ammoniu	m compounds, tri-C8-10-alkylmethyl, chlorides
freshwater	0.00015 mg/l (not defined)
marine water	0.00000002 mg/l (not defined)
sewage treatment plant	0.44 mg/l (not defined)
sediment, dry weight, freshwater	0.00063 mg/Kg (not defined)
sediment, dry weight, marine water	0.00000006 mg/Kg (not defined)
soil, dry weight	0.00000004 mg/Kg (not defined)
A alalitia wali wfa waaatia wa Tha	lists that were valid devices the association were valid as basis

[·] Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment

General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

· Breathing equipment:

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Solvent resistant gloves

Check protective gloves prior to each use for their proper condition.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

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Nitrile rubber, NBR

· Eye/face protection Tightly sealed safety glasses.

· Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

Physical state Fluid · Colour: Colourless · Smell: Ester-like

Not determined. Odour threshold: Melting point/freezing point: Not determined

Boiling point or initial boiling point and

boiling range 100 °C

· Flammability Not applicable.

Lower and upper explosion limit

Lower: 2.1 Vol % Upper: 12.5 Vol %

10 °C (80-62-6 methyl methacrylate) · Flash point:

Auto-ignition temperature: 430 °C

Decomposition temperature: Not determined.

PalaXtreme Liquid > 60 °C

·SADT

pН Mixture is non-soluble (in water).

· Viscosity: · Kinematic viscosity

Not determined. Kinematic viscosity

Not determined. · dynamic: Solubility

Water: Not miscible or difficult to mix

· Partition coefficient n-octanol/water (log

Not determined. value)

· Steam pressure at 20 °C: 47 hPa

· Vapour pressure:

Density and/or relative density

Density Not determined Relative density Not determined. · Vapour density Not determined.

· 9.2 Other information No further relevant information available.

Appearance:

Fluid Form:

· Important information on protection of health and environment, and on safety.

· Self-inflammability: Product is not selfigniting.

· Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures is possible.

· Solvent content:

Water: 0.1 % 0.1 % · Solids content:

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· Change in condition · Evaporation rate	Not determined.
· Information with regard to physical hazard	
classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
Flammable solids	Void
 Self-reactive substances and mixtures 	Void
· Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
· Substances and mixtures, which emit	
flammable gases in contact with water	Void
· Oxidising liquids	Void
Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Conditions to be avoided: No decomposition if used and stored according to specifications. 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None
 - Additional information: -

SECTION 11: Toxicological information

· 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Based on available data the classification criteria are not met

Acute toxicity based on available data, the classification criteria are not met.						
· LD/I	· LD/LC50 values that are relevant for classification:					
80-62-6 m	80-62-6 methyl methacrylate					
Oral	LD50	~7,900 mg/kg (rat)				
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)				
Inhalative	LC50/4 h	29.8 mg/l (rat)				
63225-53-	63225-53-6 2-[[(butylamino)carbonyl]oxy]ethyl acrylate					
Oral	LD50	>2,000-<5,000 mg/kg (rat) (OECD 423)				
40220-08-	40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate					
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)				
63393-96-	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides					
Oral	LD50	200 mg/kg (ATE)				
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>200-<2,000 mg/kg (rat) (OECD 401)

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- Skin corrosion/irritation
- Causes skin irritation.
- Serious eye damage/irritation Slight irritation possible
- Respiratory or skin sensitisation

May cause an allergic skin reaction.

- Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity

63225-53-6 2-[[(butylamino)carbonyl]oxy]ethyl acrylate

Oral NOAEL(C)

100 mg/kg (rat)

NOAEL (parental toxicity) 300 mg/kg/d (rat)

- STOT-single exposure
- May cause respiratory irritation.

 STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
 - · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

	· 12.1 TOXICILY	/					
Γ	· Aquatic toxicity:						
Γ	80-62-6 methyl methacrylate						
Γ	EC50/21d	49 mg/L (daphnia) (OECD 211)					
	EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)					
	NOEC / 21d	37 mg/l (daphnia) (OECD 211)					
	ErC50 / 72 h	>110 mg/l (algae) (OECD 201)					
	NOEC / 72h	110 mg/l (algae) (OECD 201)					
	NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)					
EbC50 / 72h >110 mg/l (algae) (OECD 201)							
NOEC/ 35d 9.4 mg/L (fish) (OECD 210)							
	LC50/ 35d 33.7 mg/L (fish) (OECD 210)						
Γ	63225-53-6 2	2-[[(butylamino)carbonyl]oxy]ethyl acrylate					
Γ	EC50/72h 5.98 mg/l (algae)						
LC50/96h 2.52 mg/l (fish)		2.52 mg/l (fish)					
NOEC / 72h 1.04 mg/l (algae)							
	40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate						
	EC50/48h	158.3 mg/l (daphnia) (OECD 202)					
LC50/96h 9.43 n		9.43 mg/l (fish) (OECD 203)					
	ErC50 / 72 h 25.7 mg/l (algae) (OECD 201)						
	ErC10/72h	12.9 mg/L (algae) (OECD 201)					
	63393-96-4	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides					
	EC50/48h	0.16 mg/l (daphnia) (OECD 202)					
	LC50/96h	0.15 mg/l (fish) (OECD 203)					

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ErC50 / 72 h | 0.29 mg/l (algae) (OECD 201) ErC10/72h | 0.138 mg/L (algae) (OECD 201)

· 12.2 Persistence and degradability

80-62-6 methyl methacrylate

Biodegradation 94 % /14d (not defined) (OECD 301C)

40220-08-4 (2,4,6-trioxo-1,3,5-triazinane-1,3,5-triyl)triethylene triacrylate

Biodegradation 14.5-19.7 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides

Biodegradation 10-<20 % /60d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- · 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
 - · Additional ecological information:
 - · General notes:

Do not allow product to reach ground water, water bodies or sewage system.

Avoid transfer into the environment.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

- · Uncleaned packagings:
 - Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

SECTION 14: Transport information	
· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1247
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1247 METHYL METHACRYLATE MONOMER, STABILIZED solution METHYL METHACRYLATE MONOMER, STABILIZED solution

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(Contd. of page 9) · 14.3 Transport hazard class(es) · ADR 3 (F1) Flammable liquids. · Class · Label · IMDG, IATA · Class 3 Flammable liquids. · Label 14.4 Packing group ADR, IMDG, IATA II· 14.5 Environmental hazards: Marine pollutant: No · 14.6 Special precautions for user Warning: Flammable liquids. · Kemler Number: 33 · EMS Number: *F-E,<u>S-E</u>* · Stowage Category · 14.7 Maritime transport in bulk according to IMO instruments Not applicable. · Transport/Additional information: · Limited quantities (LQ) 1L Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: Maximum net quantity per outer packaging: 500 ml · Transport category Tunnel restriction code D/E ·IMDG · Limited quantities (LQ) Excepted quantities (ÉQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 3, II · UN "Model Regulation":



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SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - · Directive 2012/18/EU
 - · Named dangerous substances ANNEX I None of the ingredients is listed.
 - · Seveso category P5c FLAMMABLE LIQUIDS
 - · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
 - Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature
SAPT: Self Accelerating Polymerisation Temperature
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Dam. 1: Serious eye damage/eye irritation — Category 1
Eye Irrit. 2: Serious eye damage/eye irritation — Category 2
Skin Sens. 1: Skin sensitisation — Category 1
Skin Sens. 1B: Skin sensitisation — Category 1B
Repr. 2: Reproductive toxicity — Category 2
STOT SE 3: Specific target organ toxicity (single exposure) — Category 3
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard — Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard — Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

* Data compared to the previous version altered.