



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

Printing date 30.01.2024

Version number 4 (replaces version 3)

Revision: 30.01.2024

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

- **1.1 Product identifier**
 - Trade name: **Palavit 55 VS 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**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
- **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
1,4-butandiol dimethacrylate
- **Hazard statements**

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
- **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking.
P261 Avoid breathing mist/vapours/spray.
P280 Wear protective gloves / eye protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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- **Additional information:**
 - 1 % of the mixture consists of component(s) of unknown toxicity.
 - Contains 1 % of components with unknown hazards to the aquatic environment.
- **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:** Product based on methacrylates

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	>90%
CAS: 2082-81-7 EINECS: 218-218-1	1,4-butandioldimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<0.25%
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 Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1) ATE: LD50 oral: 200 mg/kg	≥0.025-<0.25%
CAS: 110-16-7 EINECS: 203-742-5 Index number: 607-095-00-3 Reg.nr.: 01-2119488705-25-XXXX	maleic acid Eye Dam. 1, H318 Acute Tox. 4, H302; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 Specific concentration limit: Skin Sens. 1; H317: C ≥0.1 %	<0.1%

- **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.

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- **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
Product based on methacrylates
- **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:** No special measures required.
 - **Additional information** -

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid contact with eyes and skin.
- **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).
- **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep containers tightly sealed.
 - **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 cool (not above 25 °C).
Store in cool, dry conditions in well sealed containers.

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· 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Components with critical values that require monitoring at the workplace:

80-62-6 methyl methacrylate

WEL (Great Britain)	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

· DNELs

80-62-6 methyl methacrylate

Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
Inhalative	general population, long term, systemic	8.2 mg/Kg/d (not defined)
	worker industrial, acute, local	416 mg/m ³ (not defined)
	worker industrial, long term, systemic	348.4 mg/m ³ (not defined)
	worker industrial, long term, local	208 mg/m ³ (not defined)
	general population, acute, local	208 mg/m ³ (not defined)
	general population, long term, systemic	74.3 mg/m ³ (not defined)

2082-81-7 1,4-butandioldimethacrylate

Oral	general population, long term, systemic	2.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.2 mg/Kg/d (not defined)
Inhalative	general population, long term, systemic	2.5 mg/Kg/d (not defined)
	worker professional, long term, systemic	14.5 mg/m ³ (not defined)
	general population, long term, systemic	4.3 mg/m ³ (not defined)

131-57-7 Oxybenzone

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)
Inhalative	general population, long term, systemic	20 mg/Kg/d (not defined)
	worker industrial, long term, systemic	27.7 mg/m ³ (not defined)
	general population, long term, systemic	6.8 mg/m ³ (not defined)

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

Inhalative	worker professional, long term, systemic	0.42 mg/m ³ (not defined)
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· PNECs

80-62-6 methyl methacrylate

freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)

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sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 mg/Kg (not defined)
2082-81-7 1,4-butandioldimethacrylate	
freshwater	0.043 mg/l (not defined)
marine water	0.004 mg/l (not defined)
sewage treatment plant	2 mg/l (not defined)
sediment, dry weight, freshwater	3.12 mg/Kg (not defined)
sediment, dry weight, marine water	0.312 mg/Kg (not defined)
soil, dry weight	0.573 mg/Kg (not defined)
131-57-7 Oxybenzone	
freshwater	0.00067 mg/l (not defined)
marine water	0.000067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)
63393-96-4 Quaternary ammonium 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)

· **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 necessary 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.

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Solvent resistant gloves

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

· **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 through 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

Nitrile rubber, NBR

· **Eye/face protection** Safety glasses

· **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Colourless

· **Smell:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

-48 °C

· **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 %

· **Flash point:**

10 °C (80-62-6 methyl methacrylate)

· **Auto-ignition temperature:**

430.0 °C

· **Decomposition temperature:**

Not determined.

· **SAPT**

Palavit 55 VS liquid > 60 °C

· **SADT**

· **pH**

Mixture is non-soluble (in water).

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Kinematic viscosity**

· **dynamic at 20 °C:**

1 mPas

· **Solubility**

· **Water at 20 °C:**

1.6 g/l

· **Partition coefficient n-octanol/water (log value)**

Not determined.

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· Steam pressure at 20 °C:	47 hPa
· Vapour pressure:	
· Density and/or relative density	
· Density at 20 °C	0.940 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Fluid
· 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:	0.2 %
· 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.

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- **10.6 Hazardous decomposition products:** None
- **Additional information:**
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

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.

· **LD/LC50 values that are relevant for classification:**

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)

2082-81-7 1,4-butandioldimethacrylate

Oral	LD50	10,066 mg/kg (rat) (OECD 401)
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131-57-7 Oxybenzone

Oral	LD50	>12,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)

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

Oral	LD50	200 mg/kg (ATE) >200-<2,000 mg/kg (rat) (OECD 401)
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- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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**

131-57-7	Oxybenzone
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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

80-62-6 methyl methacrylate

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)

2082-81-7 1,4-butandioldimethacrylate

EC50/21d	14.1 mg/L (daphnia) (OECD 211)
EC50/48h	32.5 mg/l (fish)
NOEC / 21d	5.09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9.79 mg/l (algae) (OECD 201)
NOEC / 72h	2.11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4.35 mg/L (algae) (OECD 201)

131-57-7 Oxybenzone

EC50/48h	1.87 mg/l (daphnia) (OECD 202)
LC50/96h	3.8 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)
NOEC / 72h	0.18 mg/l (algae) (OECD 201)
NOEC / 96h	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)

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)
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)

2082-81-7 1,4-butandioldimethacrylate

Biodegradation 84 % /28d (not defined) (OECD 310)

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131-57-7 Oxybenzone

Biodegradation 60-70 % /28d (not defined)

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

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

· **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.

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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**

1247 METHYL METHACRYLATE MONOMER,
STABILIZED solution

· **IMDG, IATA**

METHYL METHACRYLATE MONOMER,
STABILIZED solution

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· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**
· **Label**

3 (F1) Flammable liquids.
3

· **IMDG, IATA**



· **Class**
· **Label**

3 Flammable liquids.
3

· **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:**

339

· **EMS Number:**

F-E,S-D

· **Stowage Category**

B

· **Stowage Code**

SW2 Clear of living quarters.

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **Limited quantities (LQ)**

1L

· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **Transport category**

2

· **Tunnel restriction code**

D/E

· **IMDG**

· **Limited quantities (LQ)**

1L

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· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":**

UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 3, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **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.

H302 Harmful 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.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H400 Very toxic to aquatic life.

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

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

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vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
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
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 Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
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
· *** Data compared to the previous version altered.**

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