



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

Printing date 29.07.2024

Version number 5 (replaces version 4)

Revision: 29.07.2024

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

- **1.1 Product identifier**
 - Trade name: **Signum cre-active**
 - - colourfluids
- **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** Auxiliary for 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**

Skin Sens. 1 H317 May cause an allergic skin reaction.
Repr. 1B H360Fd May damage fertility. Suspected of damaging the unborn child.
- **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**
 
GHS07 GHS08
 - **Signal word** Danger
 - **Hazard-determining components of labelling:**

triethylen glycol dimethacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
methyl methacrylate
 - **Hazard statements**

H317 May cause an allergic skin reaction.
H360Fd May damage fertility. Suspected of damaging the unborn child.
 - **Precautionary statements**

P201 Obtain special instructions before use.
P280 Wear protective gloves / eye protection.
P280 Wear protective clothing.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
 - **Additional information:**

Restricted to professional users.

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- **2.3 Other hazards -**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 109-16-0 EINECS: 203-652-6 Index number: 607-134-00-4 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥25-≤50%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X Reg.nr.: 01-2119972295-29-xxxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 1B, H360Fd Aquatic Chronic 2, H411 Skin Sens. 1B, H317	0-<1%
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	≥0.1-<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**
- **General information** No special measures required.
- **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. Then consult doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
- **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, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **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**
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** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Store cool (not above 25 °C).
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

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

79-41-4 methacrylic acid

WEL (Great Britain)	Short-term value: 143 mg/m ³ , 40 ppm Long-term value: 72 mg/m ³ , 20 ppm
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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**

109-16-0 triethylen glycol dimethacrylate

Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)

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<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	48.5 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	14.5 mg/m ³ (not defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
<i>Oral</i>	<i>general population, long term, systemic</i>	0.0833 mg/Kg (not defined)
<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	0.233 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	0.0833 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	0.822 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	0.145 mg/m ³ (not defined)
79-41-4 methacrylic acid		
<i>Oral</i>	<i>general population, long term, systemic</i>	5.35 mg/Kg (not defined)
<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	4.25 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	5.35 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	39.3 mg/m ³ (not defined)
	<i>worker industrial, long term, local</i>	44 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	11.7 mg/m ³ (not defined)
	<i>general population, long term, local</i>	8.8 mg/m ³ (not defined)
80-62-6 methyl methacrylate		
<i>Oral</i>	<i>general population, long term, systemic</i>	8.2 mg/Kg (not defined)
<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	13.67 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	8.2 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, acute, local</i>	416 mg/m ³ (not defined)
	<i>worker industrial, long term, systemic</i>	348.4 mg/m ³ (not defined)
	<i>worker industrial, long term, local</i>	208 mg/m ³ (not defined)
	<i>general population, acute, local</i>	208 mg/m ³ (not defined)
	<i>general population, long term, systemic</i>	74.3 mg/m ³ (not defined)
PNECs		
109-16-0 triethylen glycol dimethacrylate		
<i>freshwater</i>		0.016 mg/l (not defined)
<i>marine water</i>		0.002 mg/l (not defined)
<i>sewage treatment plant</i>		1.7 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>		0.185 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>		0.018 mg/Kg (not defined)
<i>soil, dry weight</i>		0.027 mg/Kg (not defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
<i>freshwater</i>		0.0014 mg/l (not defined)
<i>marine water</i>		0.00014 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>		0.115 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>		0.0115 mg/Kg (not defined)
<i>soil, dry weight</i>		0.0222 mg/Kg (not defined)

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79-41-4 methacrylic acid

freshwater	0.82 mg/l (not defined)
marine water	0.082 mg/l (not defined)
sewage treatment plant	100 mg/l (not defined)
sediment, dry weight, freshwater	3.09 mg/Kg (not defined)
sediment, dry weight, marine water	0.309 mg/Kg (not defined)
soil, dry weight	0.137 mg/Kg (not defined)

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)
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)

· **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**

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

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Hand protection**

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

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	Brown White Colourless Pink
· Smell:	Weak, characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	>150 °C
· Decomposition temperature:	Not determined.
· SADT	
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Kinematic viscosity	
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· 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:

· **Form:** Viscous

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

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive.

Not determined.

· **Solvent content:**

· **VOC EU** g/l

· **Change in condition**

· **Evaporation rate** Not determined.

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Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· 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:**
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:

1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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109-16-0 triethylen glycol dimethacrylate

Oral	LD50	8,300 mg/kg (rat)
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Dermal	LD50	>2,000 mg/kg (mouse)
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112945-52-5 Amorphous silica

Oral LD50 >10,000 mg/kg (rat)

Dermal LD50 >5,000 mg/kg (rabbit)

68187-15-5 Zirconia Praseodymium Yellow Zircon

Oral LD50 >2,200 mg/kg (rat) (OECD 401)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

79-41-4 methacrylic acid

Oral LD50 1,320 mg/kg (ATE)

Dermal LD50 1,320 mg/kg (rat) (OECD 401)

Dermal LD50 500 mg/kg (ATE)

Inhalative LC50/4 h 500-1,000 mg/kg (rabbit)

Inhalative LC50/4 h 11 mg/l (ATE)

Inhalative LC50/4 h 7.1 mg/l (rat) (OECD 403)

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)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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**
May damage fertility. Suspected of damaging the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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.
- **Additional toxicological information:**
 - **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
Repr. 1B

· **11.2 Information on other hazards**

- **Endocrine disrupting properties**

128-37-0 | 2,6-di-tert-butyl-p-cresol

List II



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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

LC50/96h >100 mg/l (fish) (OECD 203)

109-16-0 triethylen glycol dimethacrylate

EC50/21d 51.9 mg/L (daphnia) (OECD 211)

LC50/96h 16.4 mg/l (fish) (OECD 203)

NOEC / 21d 32 mg/l (daphnia) (OECD 211)

ErC50 / 72 h >100 mg/l (algae) (OECD 201)

NOEC / 72h 18.6 mg/l (algae) (OECD 201)

EbC50 / 72h 72.8 mg/l (algae) (OECD 201)

112945-52-5 Amorphous silica

LC50/96h >10,000 mg/l (fish)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

EC50/48h 10,100 mg/l (algae)

3.53 mg/l (daphnia) (OECD 202)

LC50/96h 1.4 mg/l (fish) (OECD 203)

ErC50 / 72 h >2.01 mg/l (algae) (OECD 201)

ErC10/72h 1.56 mg/L (algae) (OECD 201)

79-41-4 methacrylic acid

EC50/48h >130 mg/l (daphnia) (EPA OTS 797.1300)

LC50/96h 85 mg/l (fish) (EPA OTS 797.1400)

NOEC / 21d 53 mg/l (daphnia)

ErC50 / 72 h 45 mg/l (algae) (OECD 201)

NOEC / 72h 8.2 mg/l (algae) (OECD 201)

NOEC / 96h 12 mg/l (fish) (EPA OTS 797.1400)

NOEC / 48h 130 mg/l (daphnia) (EPA OTS 797.1300)

NOEC/ 35d 10 mg/L (fish) (OECD 210)

LC50/ 35d 42 mg/L (fish) (OECD 210)

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)

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LC50/ 35d	33.7 mg/L (fish) (OECD 210)
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· **12.2 Persistence and degradability**

1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

Biodegradation 21 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

109-16-0 triethylen glycol dimethacrylate

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Biodegradation 0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

79-41-4 methacrylic acid

Biodegradation 86 % /28d (not defined) (OECD 301D)

80-62-6 methyl methacrylate

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

· **12.3 Bioaccumulative potential**

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Bioconcentration factor (BCF) 47-55 (not defined)

· **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 undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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.

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SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.
- H360Fd May damage fertility. Suspected of damaging the unborn child.
- H411 Toxic to aquatic life with long lasting effects.

· **Abbreviations and acronyms:**

- SADT: Self Accelerating Decomposition 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

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

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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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