



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

Printing date 16.11.2022

Version number 3

Revision: 16.11.2022

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

- **1.1 Product identifier**
 - Trade name: **Charisma Smart**
- **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 Dental filling material
- **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.
- **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
 - Signal word Warning
 - Hazard-determining components of labelling:
triethylen glycol dimethacrylate
 - Hazard statements
H317 May cause an allergic skin reaction.
 - Precautionary statements
P280 Wear protective gloves / eye protection.
P280 Wear protective clothing.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
- **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**

· **Dangerous components:**

CAS: 109-16-0	triethylen glycol dimethacrylate	≥1-≤10%
EINECS: 203-652-6	Skin Sens. 1B, H317	
Reg.nr.: 01-2119969287-21-xxxx		

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CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone	(Contd. of page 1) ≥0-<0.25%
CAS: 79-41-4 EINECS: 201-204-4	Aquatic Acute 1, H400; Aquatic Chronic 2, H411 methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 ATE: LD50 oral: 1,320 mg/kg LD50 dermal: 500 mg/kg LC50/4 h inhalative: 11 mg/l Specific concentration limit: STOT SE 3; H335: C≥ 1 %	≥0-<1%
CAS: 128-37-0 EINECS: 204-881-4 Reg.nr.: 01-2119565113-46-xxxx	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥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. 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.
- **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.

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- **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**
See Section 13 for information on disposal.
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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.

· **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)
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (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)
	general population, long term, systemic	20 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	27.7 mg/m3 (not defined)
	general population, long term, systemic	6.8 mg/m3 (not defined)

79-41-4 methacrylic acid

Dermal	worker industrial, long term, systemic	4.25 mg/Kg/d (not defined)
	general population, long term, systemic	2.55 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, local	88 mg/m3 (not defined)
	worker professional, long term, systemic	29.6 mg/m3 (not defined)
	general population, long term, systemic	6.3 mg/m3 (not defined)
	general population, long term, local	6.55 mg/m3 (not defined)

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

Oral	general population, long term, systemic	0.25 mg/Kg (not defined)
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<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	<i>0.5 mg/Kg/d (not defined)</i>
	<i>general population, long term, systemic</i>	<i>0.25 mg/Kg/d (not defined)</i>
<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	<i>1.76 mg/m3 (not defined)</i>
	<i>general population, long term, systemic</i>	<i>0.435 mg/m3 (not defined)</i>

· PNECs

109-16-0 triethylen glycol dimethacrylate

<i>freshwater</i>	<i>0.016 mg/l (not defined)</i>
<i>marine water</i>	<i>0.002 mg/l (not defined)</i>
<i>sewage treatment plant</i>	<i>1.7 mg/l (not defined)</i>
<i>sediment, dry weight, freshwater</i>	<i>0.185 mg/Kg (not defined)</i>
<i>sediment, dry weight, marine water</i>	<i>0.018 mg/Kg (not defined)</i>
<i>soil, dry weight</i>	<i>0.027 mg/Kg (not defined)</i>

131-57-7 Oxybenzone

<i>freshwater</i>	<i>0.00067 mg/l (not defined)</i>
<i>marine water</i>	<i>0.000067 mg/l (not defined)</i>
<i>sewage treatment plant</i>	<i>10 mg/l (not defined)</i>
<i>sediment, dry weight, freshwater</i>	<i>0.066 mg/Kg (not defined)</i>
<i>sediment, dry weight, marine water</i>	<i>0.007 mg/Kg (not defined)</i>
<i>soil, dry weight</i>	<i>0.013 mg/Kg (not defined)</i>

79-41-4 methacrylic acid

<i>freshwater</i>	<i>0.82 mg/l (not defined)</i>
<i>marine water</i>	<i>0.82 mg/l (not defined)</i>
<i>sewage treatment plant</i>	<i>10 mg/l (not defined)</i>
<i>soil, dry weight</i>	<i>1.2 mg/Kg (not defined)</i>

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

<i>freshwater</i>	<i>0.000199 mg/l (not defined)</i>
<i>marine water</i>	<i>0.00002 mg/l (not defined)</i>
<i>sewage treatment plant</i>	<i>0.017 mg/l (not defined)</i>
<i>sediment, dry weight, freshwater</i>	<i>0.458 mg/Kg (not defined)</i>
<i>sediment, dry weight, marine water</i>	<i>0.046 mg/Kg (not defined)</i>
<i>soil, dry weight</i>	<i>0.054 mg/Kg (not defined)</i>

· 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 item 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.

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- **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:** Different according to colour
- **Smell:** Odourless
 - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** Not applicable
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Flash point:** >150 °C (109-16-0 triethylen glycol dimethacrylate)
- **Decomposition temperature:** Not determined.
- **SADT** Not determined.
- **pH** Not determined.
- **Viscosity:**
 - **Kinematic viscosity** Not determined.
 - **dynamic:** Not determined.
- **Solubility**
 - **Water:** Not miscible or difficult to mix
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure:** Not determined.
- **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:** Pasty
- **Important information on protection of health and environment, and on safety.**
 - **Self-inflammability:** Product is not selfigniting.
 - **Explosive properties:** Product is not explosive.
- **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)
Dermal	LD50	>2,000 mg/kg (mouse)

2530-85-0 3-trimethoxysilylpropyl methacrylate

Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

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68611-44-9 Silane, dichlorodimethyl-, reaction products with silica

Oral	LD50	>5,000 mg/kg (rat)
Inhalative	LC0/4h	0.477 mg/L (rat)

112945-52-5 Amorphous silica

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

131-57-7 Oxybenzone

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

79-41-4 methacrylic acid

Oral	LD50	1,320 mg/kg (rat) (OECD 401)
Dermal	LD50	500-1,000 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)

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

Oral	LD50	>6,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

- **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** Based on available data, the classification criteria are not met.
- **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.

11.2 Information on other hazards

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

- **Aquatic toxicity:**

65997-17-3 Glaspulver

EC50/72h	>1,000 mg/l (daphnia)
LC50/96h	>1,000 mg/l (fish)
ErC50 / 72 h	>1,000 mg/l (algae)
NOEC / 72h	1,000 mg/l (algae)
	1,000 mg/l (daphnia)

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

LC50/96h	>100 mg/l (fish) (OECD 203)
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109-16-0 triethylen glycol dimethacrylate

EC50/21d	51.9 mg/L (daphnia) (OECD 211)
LC50/96h	16.4 mg/l (fish) (OECD 203)

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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)

2530-85-0 3-trimethoxysilylpropyl methacrylate

EC50/48h >100 mg/l (daphnia) (EU C2.)
LC50/96h >100 mg/l (fish) (EU C.1)

68611-44-9 Silane, dichlorodimethyl-, reaction products with silica

LC50/96h >10,000 mg/l (fish) (OECD 203)
ErC50 / 72 h >10,000 mg/l (algae) (OECD 201)
EC50 / 24h >10,000 mg/l (daphnia) (OECD 202)

112945-52-5 Amorphous silica

LC50/96h >10,000 mg/l (fish) (OECD 203)
EC50 / 24h >1,000 mg/l (daphnia)

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)

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)

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

EC50/72h >0.4 mg/l (algae) (EU C.3)
EC50/21d 0.096 mg/L (daphnia) (OECD 211)
EC50/48h 0.48 mg/l (daphnia) (OECD 202)
LC50/96h >0.57 mg/l (fish) (OECD 203)
NOEC / 21d 0.069 mg/l (daphnia) (OECD 211)
NOEC / 48h 0.15 mg/l (daphnia) (OECD 202)
NOEC/ 32d 0.053 mg/L (fish) (OECD 210)

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)

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109-16-0 triethylen glycol dimethacrylate

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

2530-85-0 3-trimethoxysilylpropyl methacrylate

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

131-57-7 Oxybenzone

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

79-41-4 methacrylic acid

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

· 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** No further relevant information available.

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.

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.

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· 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**

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

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

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

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

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

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.**