



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

Printing date 21.11.2022

Version number 3

Revision: 21.11.2022

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

· **1.1 Product identifier**

· Trade name: **Charisma ABC**

· **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 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**

· Description: -

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· Dangerous components:

CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤10%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0-<0.25%
CAS: 79-41-4 EINECS: 201-204-4	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 or rash occurs: Get medical advice/attention.

· **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.

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· **Additional information -**

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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:**
Do not allow product to reach sewage system or water bodies.
Do not allow to enter the ground/soil.
- **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 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.
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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:** None.
- **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)

· **PNECs**

109-16-0 triethylen glycol dimethacrylate

freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)

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sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 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 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.

· **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 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.

· **dynamic:**

Not determined.

· **Solubility**

· **Water:**

Not miscible or difficult to mix

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· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C	2.1 g/cm ³
· 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.
· Solvent content:	
· Solids content:	78.2 %
· 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	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:** -

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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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2530-85-0 3-trimethoxysilylpropyl methacrylate

Oral	LD50	>2,000 mg/kg (rat)
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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)
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Inhalative	LC0/4h	0.477 mg/L (rat)
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112945-52-5 Amorphous silica

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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- **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)
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LC50/96h	>1,000 mg/l (fish)
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ErC50 / 72 h	>1,000 mg/l (algae)
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NOEC / 72h	1,000 mg/l (algae)
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	1,000 mg/l (daphnia)
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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)
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)

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)

2530-85-0 3-trimethoxysilylpropyl methacrylate

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

· **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** 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.

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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
 - Directive 2012/18/EU
 - Named dangerous substances - ANNEX I None of the ingredients is listed.
 - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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.

· **Date of previous version:** 31.01.2022

· **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

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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 (REACH)
PNEC: Predicted No-Effect Concentration (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.**

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