



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

Reviewed on 03/18/2025

1 Identification

· **Product identifier**

· Trade name: **Charisma**

· -

· **Application of the substance / the mixture** Dental filling material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Carcinogenicity - Category 1A H350 May cause cancer.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

triethylen glycol dimethacrylate

Quartz (SiO₂)

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

May cause cancer.

· **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of water.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

(Contd. on page 2)

CA



Safety Data Sheet
according to HPR, Schedule 1

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 1)

If skin irritation or rash occurs: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



· **HMIS-Ratings (Scale 0-4)**



· **Other hazards -**

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Composition based on methacrylates

· **Dangerous components:**

109-16-0	triethylen glycol dimethacrylate Skin Sensitizer - Category 1B, H317	≥1-≤5% w/w *
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sensitizer - Category 1B, H317	≥1-≤5% w/w *
14808-60-7	Quartz (SiO ₂) Carcinogenicity - Category 1A, H350; Specific Target Organ Toxicity - Repeated Exposure - Category 1, H372	≥0,1-<0,2% w/w *

* Actual concentration ranges are withheld as a trade secret.

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

4 First-aid measures

· **Description of first aid measures**

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **Information for doctor**

· **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

(Contd. on page 3)



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

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

(Contd. of page 2)

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
See Section 13 for disposal information.
See Section 8 for information on personal protection equipment.
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7 Handling and storage

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

8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
 - **Components with limit 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.

(Contd. on page 4)

CA



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 3)

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures** Wash hands before breaks and at the end of work.
 - **Breathing equipment:** Not required.
 - **Protection of hands:**
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 protection:** Not absolutely necessary.
 - **Body protection:** Light weight protective clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Pasty
 - **Color:** Different according to coloring
 - **Odor:** Odorless
 - **Odor threshold:** Not determined.
 - **pH-value:** Not determined.
 - **Change in condition**
 - **Melting point/Melting range:** undetermined
 - **Boiling point/Boiling range:** undetermined
 - **Flash point:** >100 °C (>212 °F)
 - **Flammability (solid, gaseous)** Not applicable.
 - **Decomposition temperature:** Not determined.
 - **Ignition temperature:** Product is not selfigniting.
 - **Danger of explosion:** Product does not present an explosion hazard.
 - **Explosion limits:**
 - **Lower:** Not determined.

(Contd. on page 5)

CA



Safety Data Sheet
according to HPR, Schedule 1

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 4)

· Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
65997-18-4 frits, chemicals		
Oral	LD50	>2000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	8300 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)

(Contd. on page 6)

CA



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 5)

Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
79-41-4 methacrylic acid		
Oral	LD50	1320 mg/kg (rat) (OECD 401)
Dermal	LD50	500-1000 mg/kg (rab)
Inhalative	LC50/4 h	7,1 mg/l (rat) (OECD 403)

· **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

- **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

14808-60-7	Quartz (SiO ₂)	1
13463-67-7	titanium dioxide	2B

· **NTP (National Toxicology Program)**

14808-60-7	Quartz (SiO ₂)	K
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- **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

65997-18-4 frits, chemicals

LC50/96h	≥3,09 mg/l (fish)
ErC50 / 72 h	≥2,4 mg/l (algae)

65997-17-3 Glaspulver

EC50/72h	>1000 mg/l (daphnia)
LC50/96h	>1000 mg/l (fish)
ErC50 / 72 h	>1000 mg/l (algae)
NOEC / 72h	1000 mg/l (algae)
	1000 mg/l (daphnia)

Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane

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)

(Contd. on page 7)

CA



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 6)

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)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate

EC50/48h	>1,2 mg/l (daphnia) (OECD 202)
LC50/96h	10,1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0,68 mg/l (algae) (OECD 201)
NOEC / 72h	0,21 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)

· Persistence and degradability

Reaction products of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane

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

109-16-0 triethylen glycol dimethacrylate

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

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate

biodegradability 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

79-41-4 methacrylic acid

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

· Behavior in environmental systems:

- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

· Additional ecological information:

· **General notes:**

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

· Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

· Other adverse effects No further relevant information available.

CA

(Contd. on page 8)



**Safety Data Sheet
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Reviewed on 03/18/2025

Trade name: Charisma

(Contd. of page 7)

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage.
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.

14 Transport information

· UN-Number	
· DOT/TDG, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT/TDG, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT/TDG, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT/TDG, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

CA
(Contd. on page 9)



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 03/18/2025

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(Contd. of page 8)

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**

H317 May cause an allergic skin reaction.

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· **Date of the latest revision of the safety data sheet** 03/18/2025 / 4

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

CA