



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

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

- **1.1 Product identifier**
 - Trade name: **Charisma**
- **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.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **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
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
 - **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
 - **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.

(Contd. on page 2)

IE



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

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Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

· **vPvB:** Not applicable.

(Contd. of page 1)

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	≥1-≤5%
CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate ----- Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	≥2.5-≤5%

· **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.

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

· **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** Not required.

· **6.2 Environmental precautions:** No special measures required.

(Contd. on page 3)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 2)

- **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)

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

Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 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)

(Contd. on page 4)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 3)

worker professional, long term, systemic	29.6 mg/m ³ (not defined)
general population, long term, systemic	6.3 mg/m ³ (not defined)
general population, long term, local	6.55 mg/m ³ (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)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)

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

freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 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 required.

· 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 not absolutely necessary

(Contd. on page 5)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

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

(Contd. of page 4)

SECTION 9: Physical and chemical properties

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

· **General Information**

· Physical state	Liquid
· 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:	>100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)
· Decomposition temperature:	Not determined.
· SADT	
· 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.

· **Solvent content:**

· **VOC EU** g/l

· **Change in condition**

· **Evaporation rate** Not determined.

(Contd. on page 6)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 5)

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:

65997-18-4 frits, chemicals

Oral	LD50	>2000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)

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

Oral	LD50	>5000 mg/kg (rat)
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(Contd. on page 7)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 6)

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-diazahexadecane-1,16-diy l bismethacrylate

Oral	LD50	>5000 mg/kg (rat) (OECD 401)
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:**

- **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**

131-57-7	Oxybenzone	List II
128-37-0	2,6-di-tert-butyl-p-cresol	List II

SECTION 12: Ecological information

· **12.1 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)

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

LC50/96h	>100 mg/l (fish) (OECD 203)
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(Contd. on page 8)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 7)

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)

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

12.2 Persistence and degradability

(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)

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

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

79-41-4 methacrylic acid

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

· **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.

(Contd. on page 9)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 8)

· **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**

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.

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:**

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· **UN "Model Regulation":**

Void

(Contd. on page 10)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 9)

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** 200 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **Regulation (EU) No 649/2012**

None of the ingredients are included.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

no information available

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

no information available

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

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**

- H317 May cause an allergic skin reaction.
- H411 Toxic to aquatic life with long lasting effects.
- EUH204 Contains isocyanates. May produce an allergic reaction.

· **Date of previous version:** 16.11.2022

· **Version number of previous version:** 4

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

(Contd. on page 11)



Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 18.03.2025

Version number 5 (replaces version 4)

Revision: 18.03.2025

Trade name: Charisma

(Contd. of page 10)

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

Skin Sens. 1: Skin sensitisation – Category 1

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

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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