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Safety Data Sheet acc. to OSHA HCS

Reviewed on 03/18/2025 Printing date 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(s) identification Classification of the substance or mixture Sensitization - Skin 1 H317 May cause an allergic skin reaction. Carcinogenicity 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 (SiÓ2) 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/vapors/sprav Contaminated work clothing must 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). If skin irritation or rash occurs: Get medical advice/attention. (Contd. on page 2)



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Wash contaminated clothing before reuse. Store locked up.

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

• NFPA ratings for USA (scale 0-4)

Health = 0Fire = 1Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = *0 Fire = 1

Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

· Chemical c	tion/information on ingredients haracterization: Mixtures tion: Composition based on methacrylates	
[.] Dangero	ous components:	
109-16-0	triethylen glycol dimethacrylate Sensitization - Skin 1B, H317	≥1- <u>≤</u> 5%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Sensitization - Skin 1B, H317	<i>≥</i> 1- <u>≤</u> 5%
14808-60-7	Quartz (SiO2) Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	<i>≥</i> 0.1-<1%

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.

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

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.

· Protective Action Criteria for Chemicals

65997-17-3	Glaspulver	15 mg/m³
109-16-0	triethylen glycol dimethacrylate	33 mg/m³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16- diyl bismethacrylate	120 mg/m ³
2530-85-0	3-trimethoxysilylpropyl methacrylate	71 mg/m³
112945-52-5	Amorphous silica	18 mg/m³
14808-60-7	Quartz (SiO2)	0.075 mg/m ³
13463-67-7	titanium dioxide	30 mg/m³
7775-14-6	sodium dithionite	30 mg/m³
80-62-6	methyl methacrylate	17 ppm
64-19-7	acetic acid	5 ppm
· PAC-2:		
65997-17-3	Glaspulver	170 mg/m³
109-16-0	triethylen glycol dimethacrylate	360 mg/m³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16- diyl bismethacrylate	1,300 mg/m ³
2530-85-0	3-trimethoxysilylpropyl methacrylate	780 mg/m³



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112945-52-5	Amorphous silica	100 mg/m³
14808-60-7	Quartz (SiO2)	8.3 mg/m3
13463-67-7	titanium dioxide	330 mg/m³
7775-14-6	sodium dithionite	330 mg/m³
80-62-6	methyl methacrylate	120 ppm
64-19-7	acetic acid	35 ppm
PAC-3:		
65997-17-3	Glaspulver	990 mg/m³
109-16-0	triethylen glycol dimethacrylate	2,100 mg/m ³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16- diyl bismethacrylate	7,900 mg/m³
2530-85-0	3-trimethoxysilylpropyl methacrylate	4,700 mg/m³
112945-52-5	Amorphous silica	630 mg/m³
14808-60-7	Quartz (SiO2)	50 mg/m3
13463-67-7	titanium dioxide	2,000 mg/m³
7775-14-6	sodium dithionite	2,000 mg/m³
80-62-6	methyl methacrylate	570 ppm
64-19-7	acetic acid	250 ppm

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.

• 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.

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· 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

Information on basic physical and che	emical 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.
· Upper:	Not determined.
Vapor pressure:	Not determined.
· Density:	Not determined
· Relative density	Not determined.



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· Vapor density · Evaporation rate	Not determined. Not determined.	
Solubility in / Miscibility with Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octano	I/water): Not determined.	
 Viscosity: dynamic: kinematic: 	Not determined. 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

·LC)/LC50 va	lues that are relevant for classification:
65997-18	8-4 frits, c	hemicals
Oral	LD50	>2000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
		s of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1- hylene)]bisoxirane
Oral	LD50	>5000 mg/kg (rat)
109-16-0	triethyle	n glycol dimethacrylate
Oral	LD50	8300 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)
72869-80		or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy thacrylate
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
79-41-4	nethacryl	ic acid
Oral	LD50	1320 mg/kg (rat) (OECD 401)
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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 (SiO2) 13463-67-7 titanium dioxide

· NTP (National Toxicology Program)

14808-60-7 Quartz (SiO2)

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

• Reproductive toxicity Based on available data, the classification criteria are not met.

· Toxicity		
· Aquatic t	oxicity:	
65997-18-4 f	rits, 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)	
	1000 mg/l (algae)	
	1000 mg/l (daphnia)	
	oducts of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1- kymethylene)]bisoxirane	
LC50/96h	>100 mg/l (fish) (OECD 203)	
109-16-0 trie	thylen 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)	
	18.6 mg/l (algae) (OECD 201)	



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2869-86-4 7	72.8 mg/l (algae) (OECD 201)
	7 0/ox 7 0 0) trimothyl 4 42 diava 2 44 diava 5 42 diazahavadaaana 4 46 diy
b	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl ismethacrylate
	>1.2 mg/l (daphnia) (OECD 202)
	10.1 mg/l (fish) (OECD 203)
	>0.68 mg/l (algae) (OECD 201)
	0.21 mg/l (algae) (OECD 201)
	acrylic acid
	>130 mg/l (daphnia) (EPA OTS 797.1300)
	85 mg/l (fish) (EPA OTS 797.1400)
	53 mg/l (daphnia)
	45 mg/l (algae) (OECD 201)
	8.2 mg/l (algae) (OECD 201)
IOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)
IOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)
Persistence	and degradability
	ducts of methacrylic acid and 2,2'-[(1-methylethylidene)bis(4,1- ymethylene)]bisoxirane
oiodegradabil	ity 21 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
09-16-0 trie	hylen glycol dimethacrylate
oiodegradabil	ity 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ismethacrylate
oiodegradabil	ity 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
'9-41-4 meth	acrylic acid
oiodegradabil	ity 86 % /28d (not defined) (OECD 301D)
 Bioaccum Mobility in Additional ed General n Do not allo system. 	ow undiluted product or large quantities of it to reach ground water, water course or sewag 3T and vPvB assessment applicable.
N 41	e effects No further relevant information available.

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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, ADR, ADN, IMDG, IATA Void · UN proper shipping name · DOT, ADR, ADN, IMDG, IATA Void Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA Void · Class · Packing group · DOT, 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.

SARA Section 313 (specific toxic chemical listings)

80-62-6 methyl methacrylate

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· Hazardous Air Pollutants	
80-62-6 methyl methacrylate	
Proposition 65	
Prop 65 - Chemicals known to cause cancer	
14808-60-7 Quartz (SiO2)	
13463-67-7 titanium dioxide	
 Chemicals known to cause reproductive toxicity for females: 	
None of the ingredients is listed.	
• Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
· Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
· Cancerogenity categories	
EPA (Environmental Protection Agency)	
80-62-6 methyl methacrylate	E, NL
· TLV (Threshold Limit Value)	
14808-60-7 Quartz (SiO2)	A2
13463-67-7 titanium dioxide	A4
NIOSH-Ca (National Institute for Occupational Safety and Health)	
14808-60-7 Quartz (SiO2)	
13463-67-7 titanium dioxide	

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

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 preparation / last revision 03/18/2025 / 4
- Abbreviations and acronyms:
- 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
- DOT: US Department of Transportation

- IATA: International Air 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

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(Contd. of particular VPVB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Sensitization - Skin 1: Skin sensitisation – Category 1 Sensitization - Skin 1B: Skin sensitisation – Category 1B Carcinogenicity 1A: Carcinogenicity – Category 1A Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) – Category 1 • * Data compared to the previous version altered.