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Safety Data Sheet acc. to OSHA HCS

Printing date 01/09/2018

Reviewed on 12/19/2017

Tel.: +49 (0)800 4372522

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)

· 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)

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

2 Hazard(s) identification

· Classification of the substance or mixture

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
 - · GHS label elements

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labeling:

triethylen glycol dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Précautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

· Classification system

NFPA ratings for USA (scale 0-4)



Health = 0 Fire = 1 Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = 0 Fire = 1 Reactivity = 0

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- Results of PBT and vPvB assessment
 - · PBT: Not applicable. · vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterization: Mixtures
 - **Description:** Composition based on methacrylates
 - · Dangerous components:

109-16-0 triethylen glycol dimethacrylate

Skin Sens. 1B, H317

0-5%

· 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.
 - · 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

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 item 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.

- 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

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· Odor threshold:	Not determined.	
· pH-value:	Not determined.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	undetermined undetermined	
· Flash point:	>130 °C (>266 °F)	
· Flammability (solid, gaseous)	Not applicable.	
· Ignition temperature:		
· Decomposition temperature:	Not determined.	
· Auto igniting:	Product is not selfigniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits: · Lower: · Upper:	Not determined. Not determined.	
· Vapor pressure:	Not determined.	
 Density: Relative density Vapor density Evaporation rate 	Not determined Not determined. Not determined. Not determined.	
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octanol/wa	ater): Not determined.	
Viscosity: dynamic: kinematic: Other information	Not determined. Not determined. 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.

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11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:
 - LD/LC50 values that are relevant for classification:

1565-94-2 Bisphenol A-bis(hydroxypropylmethacrylate)

Oral LD50 >5110 mg/kg (rat)

109-16-0 triethylen glycol dimethacrylate

Oral LD50 > 5000 mg/kg (rat)
Dermal LD50 > 2000 mg/kg (mouse)

- · 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)

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

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- Toxicity
 - · Aquatic toxicity:

109-16-0 triethylen glycol dimethacrylate

EC50/72h > 100 mg/l (algae)

- · Persistence and degradability No further relevant information available.
- · 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.

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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.

- Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.

UN-Number		
· DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name		
· DOT, ADN, IMDĞ, IATA	Void	
· ADR	Void	
Transport hazard class(es)		
· DOT, ADR, ADN, IMDG, IATA		
Class	Void	
Packing group		
· DOŤ, ĂDR, 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

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

- · TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
- · Cancerogenity categories
 - · TLV (Threshold Limit Value established by ACGIH)

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

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· GHS label elements

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

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· Hazard pictograms

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- · Signal word Warning
- · Hazard-determining components of labeling: triethylen glycol dimethacrylate
- · Hazárd statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

· 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.

· Date of preparation / last revision 01/09/2018 / 3

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the ADR: Accord europeen sur le transport des marchandises dangereuses par International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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

OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

* Data compared to the previous version altered.