

SAFETY DATA SHEETS

This SDS packet was issued with item:

074491361

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074484432 074484440 074484903 074484911 074484937 074484945 074484952 074485009 074485751 074485827
074485900 074490959 074490967 074490975 074490983 074490991 074491007 074491015 074491023 074491031
074491049 074491056 074491064 074491072 074491098 074491106 074491114 074491122 074491130 074491155
074491197 074491205 074491262 074491270 074491288 074491296 074491304 074491312 074491320 074491338
074491346 074491353 074491379 074491387 074491775 074491809 074491817 074491825 074491833 074491841
074491858

Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010

Reviewed on 08/23/2010

1 Identification of substance:

· **Product details:**

· **Trade name: Charisma**

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

· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Dr. Hoffmann
Tel.: +49 6081 959-313
Fax: +49 6081 959-223
email: marcus.hoffmann@heraeus.com

2 Hazards Identification

· **Hazard description:** not applicable

· **Information pertaining to particular dangers for man and environment** not applicable

· **Classification system**

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

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



Health = 1
Fire = 1
Reactivity = 1

· **HMIS-Ratings (Scale 0-4)**

HEALTH	0
FIRE	1
REACTIVITY	1

Health = 0
Fire = 1
Reactivity = 1

3 Composition/Data on components:

· **Chemical characterization**

· **Description:** Composition based on methacrylates

· **Dangerous components:** Void

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

4 First aid measures

· **General information** No special measures required.

· **After skin contact** Generally the product does not irritate the skin.

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

· **After swallowing** Induce vomiting and seek advice of physician.

5 Fire fighting measures

· **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.

· **Protective equipment:** No special measures required.

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· **Additional information -**

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6 Accidental release measures

- **Person-related safety precautions:** Not required.
- **Measures for environmental protection:** No special measures required.
- **Measures for cleaning/collecting:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Additional Information:**
See Section 13 for disposal information.
See Section 8 for information on personal protection equipment.

7 Handling and storage

- **Handling**
 - **Information for safe handling:** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **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).

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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.
- **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
 - **Breathing equipment:** Not required.
 - **Protection of hands:** Not required.
 - **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.
 - **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
 - **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
Natural rubber, NR
 - **Eye protection:** Not absolutely necessary.
 - **Body protection:** Light weight protective clothing

9 Physical and chemical properties:

· **General information**

· **Form:** Pasty

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· Color:	Different according to coloring
· Odor:	Odorless
· Change in condition	
· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	undetermined
· Flash point:	>130°C (>266°F)
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Density:	Not determined
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix

10 Stability and reactivity

- **Dangerous reactions** No dangerous reactions known
- **Dangerous products of decomposition:** none
- **Additional information:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

- **Acute toxicity:**
- **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.

12 Ecological information:

- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- **Product:**
- **Recommendation**
Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

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

14 Transport Information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

· **Transport/Additional information:** -

15 Regulations

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

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **Prop 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

Butyl-hydroxy-toluol 3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

Butyl-hydroxy-toluol A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Markings according to EU guidelines:**

Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).
The product is not subject to classification according to the calculation methods of the "General Classification Guideline for Preparations of the EU" as issued in the latest valid version.

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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.

· **Department issuing MSDS:** Safety department

· **Contact:**

Dr. Thiele Tel.: (+49) 6181 35-3012

email: ruediger.thiele@heraeus.com

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

USA



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

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)

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.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

Feldspar

triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapors/spray.

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

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

Get medical advice/attention if you feel unwell.

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- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



- **HMIS-Ratings (Scale 0-4)**



- **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%
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- **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 foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information -**

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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.
-

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**

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Trade name: Charisma

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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:**

>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:**

Not determined.

· **Upper:**

Not determined.

· **Vapor pressure:**

Not determined.

· **Density:**

Not determined

· **Relative density**

Not determined.

· **Vapor density**

Not determined.

· **Evaporation rate**

Not determined.

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- **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:		
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)	
Butyl-hydroxy-toluol	3
· NTP (National Toxicology Program)	
None of the ingredients is listed.	

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Trade name: Charisma

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· 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.

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.

14 Transport information

· UN-Number

· DOT, ADR, ADN, IMDG, IATA Void

· UN proper shipping name

· DOT, ADN, IMDG, IATA Void

· ADR Void

· Transport hazard class(es)

· DOT, ADR, ADN, IMDG, IATA

· Class Void

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Trade name: Charisma

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· Packing group	Void
· DOT, ADR, IMDG, IATA	
· Environmental hazards:	No
· Marine pollutant:	
· 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.

· **Carcinogenity categories**

· **TLV (Threshold Limit Value established by ACGIH)**

Butyl-hydroxy-toluol

A4

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

Feldspar
triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.
May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapors/spray.
Wear protective gloves.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
Get medical advice/attention if you feel unwell.

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Reviewed on 06/03/2017

Trade name: Charisma

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

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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** 06/03/2017 / 2

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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 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)

HMS: 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

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

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