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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 16.11.2022

Version number 5 (replaces version 4)

Revision: 16.11.2022

| | xture and of the company |
|--|----------------------------------|
| undertaking 1.1 Product identifier | |
| Trade name: Charisma | |
| | |
| 1.2 Relevant identified uses of the substance or mixture and No further relevant information available. | uses advised against |
| • Application of the substance / the mixture Dental filling ma | aterial |
| 1.3 Details of the supplier of the safety data sheet • Manufacturer/Supplier: Kulzer GmbH Laipziger Stale 2, 63450 Happy (Cormony) | Tol + + 40 (0) 900 427252 |
| Leipziger Straße 2, 63450 Hanau (Germany) | Tel.: +49 (0)800 437252 |
| • 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 lasti | ng effects. |
| • Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the GB CL • Hazard pictograms GHS07 | P regulation. |
| · 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 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/s P273 Avoid release to the environment. P280 Wear protective gloves. P362+P364 Take off contaminated clothing and wash it be | pray. |

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| • 3.2 Mixtures • Description: Product based | on methacrylates | |
|---|---|-------------------------|
| • Dangerous components: | | |
| CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxx | triethylen glycol dimethacrylate Skin Sens. 1B, H317 x | <i>≥</i> 1- <i>≤</i> 5% |
| CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxx | 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate X Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204 | <i>≥</i> 2.5-<5% |
| CAS: 79-41-4 EINECS: 201-204-4 | methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 ATE: LD50 oral: 1,320 mg/kg LD50 dermal: 500 mg/kg LC50/4 h inhalative: 11 mg/l Specific concentration limit: | <1% |

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.

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· 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.
- 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.

| 109-16-0 | riethylen 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 bismethacrylate | -3,14-dioxa-5,12-diazahexadecane-1,16-diy |
| 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) |
| 70 11 1 m | ethacrylic acid | |
| / 3-4 -4 | | 4.25 mg/Kg/d (not defined) |
| Dermal | worker industrial, long term, systemic | 4.25 mg/Ng/u (not denned) |
| | worker industrial, long term, systemic general population, long term, systemic | 2.55 mg/Kg/d (not defined) |

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Trade name: Charisma

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|--|---|---|--|
| | worker professional, long | | - · · · · · · · · · · · · · · · · · · · |
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| | general population, long | • | 6.55 mg/m3 (not defined) |
| · PN | | | |
| | cos triethylen glycol dimetha | acrivlato | |
| freshwate | | 0.016 mg/l (not | defined) |
| marine wa | | | , |
| | | 0.002 mg/l (not defined) 1.7 mg/l (not defined) | |
| - | eatment plant | | , |
| | dry weight, freshwater | 0.185 mg/Kg (n | , |
| | dry weight, marine water | | , |
| soil, dry w | | 0.027 mg/Kg (n | , |
| | bismethacrylate | - | -3,14-dioxa-5,12-diazahexadecane-1,16-di |
| freshwate | r | 0.01 mg/l (not c | defined) |
| marine wa | ater | 0.001 mg/l (not | defined) |
| sewage tr | eatment plant | 3.61 mg/l (not d | defined) |
| sediment, | dry weight, freshwater | 4.56 mg/Kg (no | t defined) |
| sediment, | dry weight, marine water | 0.46 mg/Kg (no | ot defined) |
| soil, dry w | reight | 0.91 mg/Kg (not defined) | |
| Add 8.2 Expos Appro | ditional information: The sure controls priate engineering conti | lists that were v | valid during the compilation were used as basis lata; see item 7. |
| Add 8.2 Expos Appro Indivic Ger Wa Bre Har Che reco | ditional information: The sure controls priate engineering contr dual protection measure neral protective and hyg sh hands during breaks a eathing equipment: Not r ad protection eck protective gloves prior ommended Material of gloves | ists that were v rols No further a s, such as pers ienic measures nd at the end of equired. to each use for | valid during the compilation were used as basis lata; see item 7. Sonal protective equipment S the work. |

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Trade name: Charisma

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| · VOC EU g/l · Change in condition Not determ · Evaporation rate Not determ · Information with regard to physical hazard classes Void · Explosives Void · Flammable gases Void · Oxidising gases Void · Gases under pressure Void | s not explosive. |
| Change in condition Evaporation rate Not detern Information with regard to physical hazard classes Explosives Explosives Flammable gases Void Aerosols Void Oxidising gases Void Gases under pressure | |
| Evaporation rateNot deternInformation with regard to physical hazard classesVoidExplosivesVoidFlammable gasesVoidAerosolsVoidOxidising gasesVoidGases under pressureVoid | |
| Information with regard to physical hazard classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure | . , |
| classesVoidExplosivesVoidFlammable gasesVoidAerosolsVoidOxidising gasesVoidGases under pressureVoid | mined. |
| classesVoidExplosivesVoidFlammable gasesVoidAerosolsVoidOxidising gasesVoidGases under pressureVoid | |
| Flammable gases Aerosols Oxidising gases Gases under pressure Void | |
| Flammable gases Aerosols Oxidising gases Gases under pressure Void | |
| Aerosols Void Oxidising gases Void Gases under pressure Void | |
| · Oxidising gases Void · Gases under pressure Void | |
| • Gases under pressure Void | |
| | |
| | |
| Flammable solids Void | |
| • Self-reactive substances and mixtures Void | |



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|--|------|-----------------|
| · 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.

| | | <i>n hazard classes as defined in Regulation (EC) No 1272/2008</i> Based on available data, the classification criteria are not met. |
|---------------------|------------------------|---|
| ·LD | /LC50 val | ues that are relevant for classification: |
| 65997-18 | 8-4 frits, cl | hemicals |
| Oral | LD50 | >2000 mg/kg (rat) (OECD 423) |
| Dermal | LD50 | >2000 mg/kg (rat) (OECD 402) |
| 1565-94- | 2 (1-met bismeth | hylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl) acrylate |
| Oral | LD50 | >5000 mg/kg (rat) |
| 109-16-0 | triethyler | glycol dimethacrylate |
| Oral | LD50 | 8300 mg/kg (rat) |
| Dermal | LD50 | >2000 mg/kg (mouse) |
| 72869-86 | | or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy hacrylate |
| Oral | LD50 | >5000 mg/kg (rat) (OECD 401) |
| Dermal | LD50 | >2000 mg/kg (rat) (OECD 402) |
| 79-41-4 r | nethacryl | ic acid |
| Oral | LD50 | 1320 mg/kg (rat) (OECD 401) |
| Dermal | LD50 | 500-1000 mg/kg (rab) |
| Inhalative | e LC50/4 I | n 7.1 mg/l (rat) (OECD 403) |
| · Skin (· Serio | corrosion us eye da | <i>irritation</i> Based on available data, the classification criteria are not met. mage/irritation Based on available data, the classification criteria are not met. (Contd. on page |



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· 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

None of the ingredients is listed.

| SECTION | 12: Ecological information |
|-----------------|--|
| · 12.1 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 0 | |
| 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) |
| | -methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl) |
| | smethacrylate |
| LC50/96h | >100 mg/l (fish) (OECD 203) |
| | thylen glycol dimethacrylate |
| | 51.9 mg/L (daphnia) (OECD 211) |
| | 16.4 mg/l (fish) (OECD 203) |
| | 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) |
| | ,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ismethacrylate |
| 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 meth | |
| 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) |
| | (Contd. on page |



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|--|
| 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 |
| 1565-94-2 (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-diyl 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. 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.

| 44.4 UN number of ID number | | |
|--|------|--|
| 14.1 UN number or ID number ADR, ADN, IMDG, IATA | Void | |
| 14.2 UN proper shipping name ADR, ADN, IMDG, IATA | Void | |



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| 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. | |
| <i>14.7 Maritime transport in bulk accordi IMO instruments</i> | i ng to Not applicable. | |
| · Transport/Additional information: | - | |
| · UN "Model Regulation": | Void | |

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No further relevant information available.

· 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

- H302 Harmful if swallowed.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H332 Harmful if inhaled.
- May cause respiratory irritation. H335
- H411 Toxic to aquatic life with long lasting effects.

EUH204 Contains isocyanates. May produce an allergic reaction.

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)

DNEL: Derived No-Effect Level (UK REACH) PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

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Acute Tox. 3: Acute toxicity – Category 3 Skin Corr. 1A: Skin corrosion/irritation – Category 1A Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 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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