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

Version number 2 Printing date 03.06.2017 Revision: 03.06.2017

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

- · 1.1 Product identifier
 - · Trade name: Venus Color
- · 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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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 statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection. P280

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label). P321

P362 Take off contaminated clothing and wash before reuse. P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

· Additional information:

Contains triethylen glycol dimethacrylate. May produce an allergic reaction.

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

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· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
 - · Description: -

| · Dangerous components: | | |
|--------------------------------|--|--------|
| CAS: 13760-80-0 | ytterbium trifluoride | 10-25% |
| EINECS: 237-354-2 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | |
| CAS: 21245-02-3 | 2-ethylhexyl 4-(dimethylamino)benzoate | 0-5% |
| EINECS: 244-289-3 | Eye Irrit. 2, H319 | |
| CAS: 109-16-0 | triethylen glycol dimethacrylate | < 1% |
| EINECS: 203-652-6 | Skin Sens. 1B, H317 | |
| Reg.nr.: 01-2119969287-21-0000 | | |

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.

in case or 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.
- 6.3 Methods and material for containment and cleaning up: Collect mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling

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See Section 8 for information on personal protection equipment. See Section 13 for information on disposal.

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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 under dry conditions.
- 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.

| | • | |
|---|---|----|
| U | N | LS |

109-16-0 triethylen glycol dimethacrylate

Dermal worker industr., l.te., syst. 13.9 mg/Kg/d (nd) Inhalative worker industr., l.te., syst. 48.5 mg/m3 (nd)

· PNECs

109-16-0 triethylen glycol dimethacrylate

marine water 0.0164 mg/l (nd) sedim., dw, fre.wat. 1.85 mg/Kg (nd) sedim., dw, mar.wat. 0.185 mg/Kg (nd) soil,dw 0.274 mg/Kg (nd)

- · Additional information: The lists that were valid during the compilation were used as basis.
- · 8.2 Exposure controls
 - · Personal protective equipment
 - General protective and hygienic measures

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Check protective gloves prior to each use for their proper condition.

recommended

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· Material of gloves

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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 trough 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: Safety glasses

· Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

| · 9.1 Information on basic physical and | chemical properties | |
|---|-------------------------------|--------------------|
| · General Information | | |
| Appearance: Form: | Pasty | |
| · Colour: | Different according to colour | |
| · Smell: | Odourless | |
| · Odour threshold: | Not determined. | |
| · pH-value: | Not determined. | |
| · Change in condition | | |
| Melting point/Melting range: | Not determined | |
| · Boiling point/Boiling range: | Not determined | |
| · Flash point: | > 100 °C | |
| · Inflammability (solid, gaseous) | Not applicable. | |
| · Ignition temperature: | | |
| · Decomposition temperature: | Not determined. | |
| · Self-inflammability: | Product is not selfigniting. | |
| · Danger of explosion: | Product is not explosive. | |
| · Critical values for explosion: | | |
| · Lower: | Not determined. | |
| · Upper: | Not determined. | |
| · Steam pressure: | Not determined. | |
| · Density at 20 °C | 1.9 g/cm³ | |
| · Relative density | Not determined. | |
| Vapour 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.

• 9.2 Other information No further relevant information available.

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: -

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

| · LD/LC | · LD/LC50 values that are relevant for classification: | | |
|---------------|--|-------------------------|--|
| 56744-60-6 E | 56744-60-6 Bisphenol-A-ethoxylat(4)dimethacrylat | | |
| Oral | LD50 | >2000 mg/kg (rat) | |
| 41137-60-4 d | 41137-60-4 diurethandimethacrylate | | |
| Oral | LD50 | >5000 mg/kg (rat) | |
| 68412-38-4 N | 68412-38-4 Manganese antimony titanium buff rutile | | |
| Oral | LD50 | > 10,000.00 mg/kg (rat) | |
| 21245-02-3 2 | 21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate | | |
| Oral | LD50 | >5000 mg/kg (rat) | |
| Dermal | LD50 | >2000 mg/kg (rat) | |
| Sensitisation | Sensib. | keine Sensib. (nd) | |
| 109-16-0 trie | 109-16-0 triethylen glycol dimethacrylate | | |
| Oral | LD50 | > 5000 mg/kg (rat) | |
| Dermal | LD50 | > 2000 mg/kg (mouse) | |
| Drimor | v irritan | t offort. | |

- · Primary irritant effect:
 - · Skin corrosion/irritation

Causes skin irritation.

- · Serious eye damage/irritation Causes serious eye irritation.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met. (Contd. on page 6)



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- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 - · 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
 - · Aquatic toxicity:

68412-38-4 Manganese antimony titanium buff rutile

EC50 100.00 mg/l (daphnia)

109-16-0 triethylen glycol dimethacrylate

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

- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
 - · Additional ecological information:
 - · General notes: Avoid transfer into the environment.
- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - · Recommendation Smaller quantities can be disposed with household garbage.
 - · Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- · 14.1 UN-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

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|--|--------------------------------------|--------------------|
| · 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 Transport in bulk according to Ani Marpol and the IBC Code | n ex II of 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
 - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

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)

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 Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.