



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

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.

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

Repr. 1B H360 May damage fertility or the unborn child.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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 GHS08

· **Signal word Danger**

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

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

2-ethylhexyl 4-(dimethylamino)benzoate

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H360 May damage fertility or the unborn child.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention.

P362 Take off contaminated clothing.

P405 Store locked up.

(Contd. on page 2)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: Venus Color

(Contd. of page 1)

- **Additional information:**
Restricted to professional users.
Contains isocyanates. May produce an allergic reaction.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** -

· **Dangerous components:**

CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-XXXX	(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate Aquatic Chronic 4, H413	≥10-<25%
CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥10-<25%
CAS: 21245-02-3 EINECS: 244-289-3 Reg.nr.: 01-2120766649-35-XXXX	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	≥0.3-≤5%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<0.25%

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**
In case of persistent symptoms consult doctor.
Rinse out mouth and then drink plenty of water.
- **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.

(Contd. on page 3)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: **Venus Color**

(Contd. of page 2)

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

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.
Not required.

· **DNELs**

41637-38-1 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl)oxy-2,1-ethanediyl) bismethacrylate

Oral	ge.pop., l.te, syst.	0.5 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	2 mg/Kg/d (nd)
	ge.pop., l.te, syst.	1 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	3.52 mg/m ³ (nd)
	ge.pop., l.te, syst.	0.87 mg/m ³ (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.

(Contd. on page 4)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: Venus Color

(Contd. of page 3)

· **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

· **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:** 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/freezing point:**

Not determined

· **Initial boiling point and boiling range:**

Not determined

· **Flash point:**

> 100 °C

· **Inflammability (solid, gaseous)**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Self-inflammability:**

Product is not selfigniting.

· **Explosive properties:**

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.

(Contd. on page 5)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: **Venus Color**

(Contd. of page 4)

- **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/LC50 values that are relevant for classification:**

41637-38-1 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanedioxy-2,1-ethanedioyl) bismethacrylate

Oral LD50 >2,000 mg/kg (rat) (OECD 423)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-dioyl bismethacrylate

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

68412-38-4 Manganese antimony titanium buff rutile

Oral LD50 >10,000 mg/kg (rat)

21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral LD50 14,900 mg/kg (rat)

- **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes skin irritation.
 - **Serious eye damage/irritation**
Causes serious eye irritation.
 - **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 1B
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

(Contd. on page 6)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: Venus Color

(Contd. of page 5)

· **Carcinogenicity** Based on available data, the classification criteria are not met.

· **Reproductive toxicity**

21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral NOAEL (Fertility) 50 mg/kg/d /64 d (rat) (OECD 421)

· **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:**

41637-38-1 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl)oxy-2,1-ethanediyl bismethacrylate

EC50/72h >100 mg/l (algae) (OECD 201)

EC50/48h >100 mg/l (daphnia) (OECD 202)

LC50/96h >100 mg/l (fish) (OECD 203)

NOEC 28d 14.3 mg/l (bacteria)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

LC50/96h 10.1 mg/l (fish)

68412-38-4 Manganese antimony titanium buff rutile

EC50 100 mg/l (daphnia)

· **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

(Contd. on page 7)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: Venus Color

(Contd. of page 6)

· 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.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	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.
 - **Directive 2012/18/EU**
 - **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.
- H360 May damage fertility or the unborn child.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.

· **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 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)
- DNEL: Derived No-Effect Level (REACH)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

(Contd. on page 8)



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

Printing date 06.06.2021

Version number 3

Revision: 06.06.2021

Trade name: Venus Color

(Contd. of page 7)

Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
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
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
*** Data compared to the previous version altered.**

IE