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

Printing date 16.11.2022 Version number 3 (replaces version 2) Revision: 16.11.2022

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 GB 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-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

2-ethylhexyl 4-(dimethylamino)benzoate

triethylen glycol dimethacrylate

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.

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· Additional information:

Restricted to professional users.

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

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

Description:

· Description: -		
· Dangerous components:		
CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-xxxx	bisphenol A polyethnylene glycol diether dimethacrylate Aquatic Chronic 4, H413	≥10-<25%
	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
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 EUH204	≥10-<25%
	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	≥0.3-≤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

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.

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- · 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
 - - 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.

· DNI	ELs			
41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate				
Oral	general population, long term, systemic	5 mg/Kg (not defined)		
Dermal	worker industrial, long term, systemic	140 mg/Kg/d (not defined)		
	general population, long term, systemic	50 mg/Kg/d (not defined)		
Inhalative	worker industrial, long term, systemic	98.7 mg/m3 (not defined)		
	general population, long term, systemic	17.4 mg/m3 (not defined)		
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate				
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)		
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· PNECs	
72869-86-4 7,7,9(or 7,9,9)-trimeta bismethacrylate	hyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)

[·] Additional information: The lists that were valid during the compilation were used as basis.

0.91 mg/Kg (not defined)

· 8.2 Exposure controls

soil, dry weight

- · Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures
 - Wash hands during breaks and at the end of the work.
 - · Breathing equipment: Not required.
 - · Hand protection

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 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/face 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

Physical state Fluid

· Colour: Different according to colour

· Smell: Odourless

· Odour threshold: Not determined. · Melting point/freezing point: Not determined

Boiling point or initial boiling point and

boiling range Not determined Flammability Not applicable.

· Lower and upper explosion limit

· Lower: Not determined.

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(Contd. of page 4) Not determined. · Upper: >100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-· Flash point: 4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate) Decomposition temperature: Not determined. SADT Not determined. pН Viscosity: Not determined. · Kinematic viscosity Not determined. dynamic: Solubility Not miscible or difficult to mix Water: · Partition coefficient n-octanol/water (log Not determined. Not determined. Steam pressure: · Density and/or relative density Density at 20 °C 1.9 g/cm3 · Relative density Not determined. · Vapour density Not determined. · 9.2 Other information No further relevant information available. Appearance: Form: Pasty · Important information on protection of health and environment, and on safety. Self-inflammability: Product is not selfigniting. Explosive properties: Product is not explosive. Change in condition Evaporation rate Not determined. · Information with regard to physical hazard classes Void Explosives Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void Flammable solids Void · Self-reactive substances and mixtures Void · 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.

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- · 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 hazard classes as defined in Regulation (EC) No 1272/2008
 - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values	that are relevant for classification:
627 20 1 bianhanal	A nelvethnylane alveel diether dimethes

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate LD50 >2000 mg/kg (rat) (OECD 423)

Dermal LD50 >2000 mg/kg (rat) (OECD 402)

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

LD50 >5000 mg/kg (rat) (OECD 401) Oral

Dermal LD50 >2000 mg/kg (rat) (OECD 402)

68412-38-4 Manganese antimony titanium buff rutile

Oral LD50 >10000 mg/kg (rat)

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

LD50 14900 mg/kg (rat)

- · Skin corrosion/irritation
- Causes skin irritation.
- Serious eye damage/irritation

- Causes serious eye irritation.
 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

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.
- Additional toxicological information:
 - CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Repr. 1B
- 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.



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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic t	oxicity:	
41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate		
EC50/72h	>100 mg/l (algae) (OECD 201)	
LL50/96h	>100 mg/L (fish) (OECD 203)	
EL50/48h	>100 mg/L (daphnia) (OECD 202)	
EL50/72h	>100 mg/L (algae) (OECD 201)	
NOEC / 21d	≥22.4 mg/l (daphnia) (OECD 211)	
NOEC 28d	14.3 mg/l (bacteria)	
NOELR	100 mg/L /48h (daphnia) (OECD 202)	
72869-86-4 7	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl	
bismethacrylate		
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)	
68412-38-4 N	Manganese antimony titanium buff rutile	
EC50	100 mg/l (daphnia)	

· 12.2 Persistence and degradability

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Biodegradation 24 % /28d (not defined) (OECD 301D)

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)

- 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: Avoid transfer into the environment.

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.



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SECTION 14: Transport information	on	
14.1 UN number or ID number ADR, IMDG, IATA	Void	
14.2 UN proper shipping name ADR, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
· ADR, IMDG, IATA		
· Class	Void	
· 14.4 Packing group	Vola	
· ADR, IMĎĞ, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according IMO instruments	y 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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

May damage fertility or the unborn child. H360

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

May cause long lasting harmful effects to aquatic life. H413

EUH204 Contains isocyanates. May produce an allergic reaction.

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

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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)
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
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. 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 aftered

* Data compared to the previous version altered.