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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

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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-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/ hearing 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.

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P405 Store locked up.
· **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:** -

· **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%
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 EUH204	≥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**
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***
· ***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.*

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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 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)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
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)
soil, dry weight	0.91 mg/Kg (not defined)

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

· **8.2 Exposure controls**
· **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

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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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· **Upper:**	Not determined.
· **Flash point:**	>100 °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)
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **dynamic:**	Not determined.
· **Solubility**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure:**	Not determined.
· **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**	
· **Explosives**	Void
· **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:** -

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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:**		
41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate		
Oral	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		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
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		
Oral	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 toxicity:**	
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 7,7,9(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 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

· **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**	
· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	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.
· **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.
EUH204 Contains isocyanates. May produce an allergic reaction.
· **Date of previous version:** 06.06.2021
· **Version number of previous version:** 2

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· ***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
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 (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. 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.***