

SAFETY DATA SHEETS

This SDS packet was issued with item:

074565339

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

074565289

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071114750 074515271 074515289 074562575 074562583 074562591 074562609 074562617 074562625 074562633
074562641 074562658 074562666 074562674 074562682 074562724 074562732 074562740 074562757 074562765
074562773 074562799 074562807 074562815 074562823 074562831 074562849 074562856 074562880 074562898
074562906 074562914 074562922 074562930 074562948 074562955 074562963 074562971 074562989 074562997
074563003 074563011 074563029 074563037 074563045 074563052 074563060 074563078 074563086 074563094
074563102 074563110 074563128 074563136 074563144 074563300 074563318 074563326 074563334 074564704
074564761 074564829 074564852 074564878 074565255 074565263 074565271 074565305 074565313 074565321
074565347 074565354 074565362 074565370 074565388 074565396 074565404 074565412 074565420 074565438
074565446 074565552 074565560 074565578 074565586 074565594 074565602 074565610 074565628 074565636
074565644 074565651 074565669 074565677 074567004 074567012 074567020 074567038 074567046 074567053
074567061 074567079 074567087 074567095 074567103 074567111 074567129 074567137 074567145 074567210
074567509 074567517 074567525 074567533 074567541 074567558 074567707 074567715 074567723 074567731
074567749 272427276 273004835 273004836

Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2015

Reviewed on 08/04/2015

1 Identification

- **Product identifier**
 - **Trade name: Venus Diamond**
 - **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
- **Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau Tel.: 0800 4372522
 - **Information department:**
Marc Henn
Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542
e-mail: marc.henn@kulzer-dental.com
 - **Emergency telephone number:**
Emergency CONTACT (24-Hour-Number)
GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Label elements**
 - **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediy) ester triethylenglycoldimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system**
 - **NFPA ratings for USA (scale 0-4)**



Health = 0
Fire = 1
Reactivity = 0

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USA

Safety Data Sheet
acc. to OSHA HCS

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Trade name: Venus Diamond

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HMIS-Ratings (Scale 0-4)

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description: -**

Dangerous components:

861437-11-8	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester	10-25%
109-16-0	triethylglycoldimethacrylate	0-5%

- **Additional information** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

Description of first aid measures

- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately 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.
If symptoms persist consult doctor.
Seek immediate medical advice.

Information for doctor

- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

Extinguishing media

- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

Advice for firefighters

- **Protective equipment:** No special measures required.

Additional information -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Dilute with plenty of water.

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USA

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 08/04/2015

Reviewed on 08/04/2015

Trade name: Venus Diamond

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- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
Send for recovery or disposal in suitable receptacles.
- **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 disposal information.

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Please observe the additional instructions in the product's instructions for use.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
 - **Components with limit 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.
· **Additional Information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of 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
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
 - **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 gloves made of the following materials are suitable:**
Natural rubber, NR

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USA

Safety Data Sheet
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Reviewed on 08/04/2015

Trade name: Venus Diamond

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- **Eye protection:** Safety glasses
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** White
Yellowish

- **Odor:** Odorless
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condltion**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** undetermined

· **Flash point:** > 165 °C (> 329 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Auto Igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 2.23 g/cm³ (18.609 lbs/gal)

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water:** Not miscible or difficult to mix

· **Partitlon coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none

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USA

Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2015

Reviewed on 08/04/2015

Trade name: **Venus Diamond**

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· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional Information:	-
· UN "Model Regulation":	-

15. Regulatory Information

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

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.

· Cancerogenity categories

· TLV (Threshold Limit Value established by ACGIH)

Butyl-hydroxy-toluol

A4

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS07

· Signal word Warning

· Hazard-determining components of labeling:

2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester
triethylenglycoldimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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USA

Safety Data Sheet
acc. to OSHA HCS

Printing date 08/04/2015

Reviewed on 08/04/2015

Trade name: Venus Diamond**Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**

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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.

Date of preparation / last revision 08/04/2015 / -

Abbreviations and acronyms:

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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

*** Data compared to the previous version altered.**

USA



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 06/06/2021

Reviewed on 06/06/2021

1 Identification

· **Product identifier**

· Trade name: **VENUS Diamond flow**

· -

· Application of the substance / the mixture Dental filling material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· **Classification of the substance or mixture**

Skin Irritation - Category 2

H315 Causes skin irritation.

Eye Irritation - Category 2A

H319 Causes serious eye irritation.

Skin Sensitizer - Category 1

H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 1B

H360 May damage fertility or the unborn child.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

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

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

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May damage fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves / eye protection / face protection.

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).

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

Store locked up.

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CA



Safety Data Sheet
according to HPR, Schedule 1

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: **VENUS Diamond flow**

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- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



- **HMIS-Ratings (Scale 0-4)**



- **Other hazards -**

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description: -**

- **Dangerous components:**

13760-80-0	ytterbium trifluoride Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	≥10-<20% w/w *
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sensitizer - Category 1B, H317	10-25% w/w *
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate Reproductive Toxicity - Category 1B, H360	≥0.1-<0.2% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- **Description of first aid measures**

- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately 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.
If symptoms persist consult doctor.
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: **VENUS Diamond flow**

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5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 13 for disposal information.
See Section 8 for information on personal protection equipment.
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Store in dry conditions.
Keep cool, if possible (not above 25 °C).
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/ Personal protection

- **Control parameters**
 - **Components with limit 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.
 - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Wash hands before breaks and at the end of work.
 - **Breathing equipment:** Not required.

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**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: VENUS Diamond flow

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· **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Color:**

White

Yellowish

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

undetermined

· **Flash point:**

> 100 °C (> 212 °F)

· **Flammability (solid, gaseous)**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Auto igniting:**

Product is not selfigniting.

· **Danger of explosion:**

Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Vapor pressure:**

Not determined.

· **Density at 20 °C (68 °F):**

1.9 g/cm³ (15.8555 lbs/gal)

· **Relative density**

Not determined.

· **Vapor density**

Not determined.

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Safety Data Sheet
according to HPR, Schedule 1

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: **VENUS Diamond flow**

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**
· **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
41637-38-1 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate		
Oral	LD50	>2,000 mg/kg (rat) (OECD 423) read-across
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402) read-across
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate		
Oral	LD50	14,900 mg/kg (rat)

- **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)	
7631-86-9	silicon dioxide, chemically prepared

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**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: **VENUS Diamond flow**

128-37-0 2,6-di-tert-butyl-p-cresol

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **Reproductive toxicity**

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

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

12 Ecological information

· **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)

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:** Avoid transfer into the environment.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**

· **DOT/TDG, ADR, ADN, IMDG, IATA** Void

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**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 06/06/2021

Reviewed on 06/06/2021

Trade name: VENUS Diamond flow

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- | | |
|--|-----------------|
| · UN proper shipping name
· DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· DOT, ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· DOT/TDG, ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

- Sara

- **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

- **Date of the latest revision of the safety data sheet** 06/06/2021 / 3

- **Abbreviations and acronyms:**

- IMDG: International Maritime Code for Dangerous Goods

- DOT: US Department of Transportation

- IATA: International Air Transport Association

- 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)

- NFPA: National Fire Protection Association (USA)

- HMIS: Hazardous Materials Identification System (USA)

- LC50: Lethal concentration, 50 percent

- LD50: Lethal dose, 50 percent

- PBT: Persistent, Bioaccumulative and Toxic

- vPvB: very Persistent and very Bioaccumulative

- *** Data compared to the previous version altered.**



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

· **1.1 Product identifier**

· Trade name: **Venus Diamond**

· **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 Sens. 1 H317 May cause an allergic skin reaction.

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

· **Signal word** Warning

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

2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester

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

triethylen glycol dimethacrylate

· **Hazard statements**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

GB

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 945656-78-0	2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl)bis(methyleneoxycarbonylamino-2,1-ethanediy)] ester Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥10-<25%
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	≥2.5-<5%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<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.
Seek immediate medical advice.

· **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**

Formation of toxic gases is possible during heating or in case of fire.

· **5.3 Advice for firefighters**

- **Protective equipment:** No special measures required.
- **Additional information** -

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Dilute with much water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Send for recovery or disposal in suitable containers.
- **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**
Please observe the additional instructions in the product's instructions for use.
 - **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:** None.
- **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		
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)
109-16-0 triethylen 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)
131-57-7 Oxybenzone		
Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)

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Inhalative	general population, long term, systemic	20 mg/Kg/d (not defined)
	worker industrial, long term, systemic	27.7 mg/m3 (not defined)
	general population, long term, systemic	6.8 mg/m3 (not defined)

· PNECs

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-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)

109-16-0 triethylen glycol dimethacrylate

freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)

131-57-7 Oxybenzone

freshwater	0.00067 mg/l (not defined)
marine water	0.00067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)

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

· 8.2 Exposure controls

· Appropriate engineering controls No further data; see item 7.

· Individual protection measures, such as personal protective equipment

· General protective and hygienic measures

Instantly remove any soiled and impregnated garments.

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

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

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.

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- **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/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:** White
Yellowish
Odourless
- **Smell:**
· **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.
· **Upper:** Not determined.
- **Flash point:** >150 °C (109-16-0 triethylen glycol dimethacrylate)
Not determined.
- **Decomposition temperature:** Not determined.
- **SADT** Not determined.
- **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** 2.23 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.

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- **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.
- **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:**

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

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

109-16-0 triethylen glycol dimethacrylate

Oral LD50 8,300 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (mouse)

131-57-7 Oxybenzone

Oral LD50 >12,800 mg/kg (rat) (OECD 401)

Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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 toxicity:**

65997-17-3 Glaspulver

EC50/72h	>1,000 mg/l (daphnia)
LC50/96h	>1,000 mg/l (fish)
ErC50 / 72 h	>1,000 mg/l (algae)
NOEC / 72h	1,000 mg/l (algae) 1,000 mg/l (daphnia)

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)

109-16-0 triethylen glycol dimethacrylate

EC50/21d	51.9 mg/L (daphnia) (OECD 211)
LC50/96h	16.4 mg/l (fish) (OECD 203)
NOEC / 21d	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)

131-57-7 Oxybenzone

EC50/48h	1.87 mg/l (daphnia) (OECD 202)
LC50/96h	3.8 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)
NOEC / 72h	0.18 mg/l (algae) (OECD 201)
NOEC / 96h	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)

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· **12.2 Persistence and degradability**

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

Biodegradation 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

109-16-0 triethylen glycol dimethacrylate

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

131-57-7 Oxybenzone

Biodegradation 60-70 % /28d (not defined)

· **12.3 Bioaccumulative potential**

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

· **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 product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID 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

· **14.4 Packing group**

· **ADR, IMDG, IATA** Void

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

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- | | |
|---|-----------------|
| · 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.
- **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**

- H317 May cause an allergic skin reaction.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful 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)
- 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 Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1B: Skin sensitisation – Category 1B
- 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

- *** Data compared to the previous version altered.**