# **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 074563112 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 074567633 074567061 074567079 074567087 074567095 074567103 074567111 074567129 074567137 074567145 074567210 074567509 074567517 074567525 074567533 074567541 074567558 074567707 074567715 074567723 074567731 074567749 272427276 273004835 273004836

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

Printing date 08/04/2015

Reviewed on 08/04/2015

Tel.: 0800 4372522

#### 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

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-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.

Classification system

NFPA ratings for USA (scale 0-4)



Health = 0 Fire = 1Reactivity = 0

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

Printing date 08/04/2015

Reviewed on 08/04/2015

# Trade name: Venus Diamond

· HMIS-Ratings (Scale 0-4)

(Contd. of page 1)

HEALTH 0 T

Health = 0 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) 10-25% bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

109-16-0 triethylenglycoldimethacrylate

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

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

#### Printing date 08/04/2015

Reviewed on 08/04/2015

#### Trade name: Venus Diamond

(Contd. of page 2)

· 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 hyglenic 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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#### Safety Data Sheet acc. to OSHA HCS

Printing date 08/04/2015

Reviewed on 08/04/2015

# Trade name: Venus Diamond

(Contd. of page 3)

· Eye protection: Safety glasses · Body protection: Light weight protective clothing

Physical and chemical propert	
Information on basic physical and cl	hemical properties
General Information	
Appearance:	Dook.
Form: Color:	Pasty White
Color.	Yellowish
· Odor:	Odoriess
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
· Melting point/Meiting 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
· Partition coefficient (n-octanol/wa	nter): 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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#### Safety Data Sheet acc. to OSHA HCS

Printing date 08/04/2015

Reviewed on 08/04/2015

Trade name: Venus Diamond (Contd. of page 4) · Additional information: -

## 11 Toxicological information

- · Information on toxicological effects
  - · Acute toxicity:
    - Primary Irritant effect:
      - · on the skin: No imitant effect.
      - · on the eye: No imitating effect.
    - Sensitization: Sensitization possible through skin contact.
  - Additional toxicological information: Irritant
    - · Carcinogenic categories

Carcinogenic categories	
· IARC (International Agency for Research on Cancer)	
7631-86-9 silicon dioxide, chemically prepared	3
Butyl-hydroxy-toluol	3
· NTP (National Toxicology Program)	
None of the ingredients is listed.	

· OSHA-Ca (Occupational Safety & Health Administration) None of the Ingradients is listed.

# 12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
  · Persistence and degradability No further relevant information available.
- Behavior in environmental systems:
  Bloaccumulative potential No further relevant information available.
  Mobility in soil No further relevant information available.
- · Additional ecological information: General notes:

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · 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

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

# 14 Transport information **UN-Number** DOT, ADR, ADN, IMDG, IATA Void (Contd. on page 6)

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

Printing date 08/04/2015

Reviewed on 08/04/2015

# Trade name: Venus Diamond

		(Contd. of pag
· 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 MARPOL73/78 and the IBC Code	II of Not applicable.	
· Transport/Additional Information:	<del>-</del>	
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



- · Signal word Waming
- · Hazard-determining components of labeling:

2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyi) 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 imitation or rash occurs: Get medical advice/attention.

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

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

Printing date 08/04/2015

Reviewed on 08/04/2015

# Trade name: Venus Diamond

(Contd. of page 6)

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.

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

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 Maintime Code for Dangerous Goods
DOT: US Department of Transport Association
IATA: International Air Transport Association
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: Hezardous 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.



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# Safety Data Sheet according to HPR, Schedule 1

Printing date 06/06/2021

Reviewed on 06/06/2021

Tel.: +49 (0)800 4372522

### 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)

· 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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# Safety Data Sheet according to HPR, Schedule 1

Printing date 06/06/2021

Reviewed on 06/06/2021

# Trade name: VENUS Diamond flow

· Classification system

NFPA ratings for USA (scale 0-4)



Health = 2 Fire = 1 Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = 2 Fire = 1 Reactivity = 0

· Other hazards -

# 3 Composition/Information on ingredients

- · Chemical characterization: Mixtures
  - · Description: -

20011611111			
· Danger	· 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	3 2-ethylhexyl 4-(dimethylamino)benzoate Reproductive Toxicity - Category 1B, H360	≥0.1-<0.2% w/w *	

<sup>\*</sup> 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.

CA ·



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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

(Contd. of page 2)

# 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.

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### 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.

(Contd. on page 4)



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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

(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

# 9 Physical and chemical properties

· Information on basic physical and chemical properties	
General Information	
Appearance:	Death
· Form: · Color:	Pasty White
Color:	Yellowish
· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition · Melting point/Melting range: · Boiling point/Boiling range:	undetermined 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. Not determined.
· Upper:	
· 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.

(Contd. on page 5)



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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

(Contd. of page 4)

• Evaporation rate Not determined.

· 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.

· 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:

· L	.D/LC5	0 values that are relevant for classification:
41637-	bi	-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyloxy-2,1-ethanediyl) smethacrylate
Oral	LD50	>2,000 mg/kg (rat) (OECD 423) read-across

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-diazahexadecane-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

(Contd. of page 5)

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

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-ethanediyloxy-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

(Contd. on page 7)



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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

		(Contd. of page 6)
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 MARPOL73/78 and the IBC Code	ll of 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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# Safety data sheet according to 1907/2006/EC, Article 31

Printing date 16.11.2022 Version number 4 (replaces version 3) Revision: 16.11.2022

# 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

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



- · 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.



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Trade name: Venus Diamond

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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-ethanediyl)] 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 -

GB



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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.

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 1	riethylen 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)
		(Contd. on p



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		(Contd. of page 3
	general population, long	
Inhalative	worker industrial, long te	rm, systemic 27.7 mg/m3 (not defined)
	general population, long	term, systemic 6.8 mg/m3 (not defined)
· PNI	ECs	
72869-86-	4 7,7,9(or 7,9,9)-trimet bismethacrylate	hyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
freshwater	r	0.01 mg/l (not defined)
marine wa	ter	0.001 mg/l (not defined)
sewage tre	eatment 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 w	soil, dry weight 0.91 mg/Kg (not defined)	
109-16-0 t	109-16-0 triethylen glycol dimethacrylate	
freshwater	r	0.016 mg/l (not defined)
marine wa	ter	0.002 mg/l (not defined)
sewage tre	eatment plant	1.7 mg/l (not defined)
sediment,	dry weight, freshwater	0.185 mg/Kg (not defined)
sediment,	sediment, dry weight, marine water 0.018 mg/Kg (not defined)	
soil, dry w	eight	0.027 mg/Kg (not defined)
131-57-7 (	Oxybenzone	
freshwater	r	0.00067 mg/l (not defined)
marine wa	ter	0.000067 mg/l (not defined)
sewage tre	eatment 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 w	eight	0.013 mg/Kg (not defined)

<sup>·</sup> 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 preparation of several substances, the resistance of the application.

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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: White Yellowish · Smell: Odourless

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

· Boiling point or initial boiling point and

Not determined boiling range · Flammability Not applicable. · Lower and upper explosion limit

Lower: Not determined. Not determined. · Upper:

>150 °C (109-16-0 triethylen glycol · Flash point:

dimethacrylate)

Decomposition temperature: Not determined.

SADT

· pH Not determined.

Viscosity:

Kinematic viscosity Not determined. Not determined. · dynamic: · 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 t	oxicity:
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 k	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl pismethacrylate
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 trie	thylen 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)
	(Contd. on page 8



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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-diazahexadecane-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.

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 IMO instruments	<b>g to</b> 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.

Toxic to aquatic life with long lasting effects. 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

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.