## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

074565305

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 074563961 074564019 074564027 074564704 074564761 074564829 074564852 074564878 074565255 074565263 074565271 074565313 074565321 074565339 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 272427276

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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/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
· 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 1907/2006/EC, Article 31

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

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

- · 1.1 Product identifier
  - · Trade name: Venus flow
- · 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:

Heraeus Kulzer GmbH

Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

- Informing department: E-Mail: msds@kulzer-dental.com

• 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number):GBK GmbH +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.

- · 2.2 Label elements
  - Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

triethylenglycoldimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label). P363 Wash contaminated clothing before reuse.

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

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

· 2.3 Other hazards -

- · Results of PBT and vPvB assessment
  - · PBT: Not applicable.
  - vPvB: Not applicable.

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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

(Contd. of page 1)

# **SECTION 3: Composition/information on ingredients**

- · 3.2 Chemical characterisation: Mixtures
  - · **Description:** Product based on methacrylates

· Dangerous components:		
CAS: 109-16-0	triethylenglycoldimethacrylate	10-25%
EINECS: 203-652-6	Skin Sens. 1B, H317	
Reg.nr.: 01-2119969287-21-0000	·	
CAS: 24650-42-8	2,2-Dimethoxy-1,2-diphenyl-ethan-1-on	< 1%
EINECS: 246-386-6	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

<sup>·</sup> 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
  - · General information Instantly remove any clothing soiled by the product.
  - · After inhalation Supply fresh air; consult doctor in case of symptoms.
  - · After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- · After eye contact Rinse opened eye for several minutes under running water. Then consult doctor.
- · After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

# SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents

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

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
  - · Protective equipment: No special measures required.
  - Additional information -

#### SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- · 6.2 Environmental precautions:

Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

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· 6.4 Reference to other sections

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

-

# SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Wear protective equipment. Keep unprotected persons away.

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: Store cool (not above 25 °C).
- · 7.3 Specific end use(s) No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 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.

- Additional information: The lists that were valid during the compilation were used as basis.
- · 8.2 Exposure controls
  - · Personal protective equipment
    - General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

- 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

Solvent resistant gloves

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.

(Contd. on page 4)

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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

(Contd. of page 3)

· 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 protection: Tightly sealed safety glasses.

Body protection: Light weight protective clothing

#### SECTION 9: Physical and chemical properties · 9.1 Information on basic physical and chemical properties **General Information** Appearance: Form: Pastv · Colour: Different according to colour · Smell: Characteristic · Odour threshold: Not determined. · pH-value: Not determined. · Change in condition Melting point/Melting range: Not determined Boiling point/Boiling range: Not determined >160 °C · Flash point: · Inflammability (solid, gaseous) Not applicable. · Ignition temperature: Decomposition temperature: Not determined. · Self-inflammability: Product is not selfigniting. · Danger of explosion: Product is not explosive. · Critical values for explosion: · Lower: Not determined. · Upper: Not determined. · Steam pressure: Not determined. · Density at 20 °C 1.8 g/cm<sup>3</sup> 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/water): Not determined. · Viscosity: Not determined. dynamic: · kinematic: Not determined.

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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

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· Solvent content:

 Solids content: >60 %

No further relevant information available. 9.2 Other information

# 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:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

## SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.
    - Primary irritant effect:
      - 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

Guinea-Pig Maximisation Test (OECD 406): negative

May cause an allergic skin reaction.

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  - 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.

## SECTION 12: Ecological information

- · 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
  - Additional ecological information:
- General notes: Avoid transfer into the environment. 12.5 Results of PBT and vPvB assessment
- - · PBT: Not applicable.
  - · vPvB: Not applicable.

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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

(Contal o

· 12.6 Other adverse effects No further relevant information available.

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## 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.

· European waste catalogue

18 01 06 chemicals consisting of or containing dangerous substances

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

4.4.4 LINI Nivembor		
14.1 UN-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	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Annex Marpol and the IBC Code	<b>( II of</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.

GB

(Contd. on page 7)



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

Printing date 20.01.2016 Version number 2 Revision: 30.12.2015

Trade name: Venus flow

(Contd. of page 6)

## 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.

H410 Very toxic to aquatic life with long lasting effects.

#### · 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

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)
PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

\* Data compared to the previous version altered.



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# Safety Data Sheet acc. to OSHA HCS

Printing date 11/28/2017

Reviewed on 11/28/2017

Tel.: +49 (0)800 4372522

## 1 Identification

- · Product identifier
  - · Trade name: Venus Diamond
    - · 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)

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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

triethylen glycol dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

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

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

· Classification system

· NFPA ratings for USA (scale 0-4)



Health = 0 Fire = 1 Reactivity = 0

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· HMIS-Ratings (Scale 0-4)

HEALTH 0
FIRE 1
REACTIVITY 0

Health = 0 Fire = 1 Reactivity = 0

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

## 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
  - · Description: -

•	s components:	
	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester Skin Sens. 1, H317	10-25%
109-16-0	triethylen glycol dimethacrylate	0-5%
	Skin Sens. 1B, H317	

· Additional information For the wording of the listed hazard 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 -

ПСА

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## 6 Accidental release measures

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

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

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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:

Button Hills to be observed.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Button Hills to be observed.

Nitrile rubber, NBR

· Eye protection: Safety glasses

· Body protection: Light weight protective clothing

# 9 Physical and chemical properties

Information on basic physical and che	emical properties
General Information	
· Appearance: · Form:	Pasty
· Color:	White
· Color.	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:	> 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 (18.60935 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/wat	er): Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.



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· 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:

861437-11-82-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

LD50 >2000 mg/kg (rat)

109-16-0 triethylen glycol dimethacrylate

LD50 > 5000 mg/kg (rat)

Dermal LD50 > 2000 mg/kg (mouse)

- · Primary irritant effect:
  - on the skin: No irritant effect.
- on the eye: No irritating effect.Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: Irritant
  - · Carcinogenic categories

7631-86-9 silicon dioxide, chemically prepared

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

3

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

## 12 Ecological information

- · Toxicity
  - · Aquatic toxicity:

861437-11-82-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

EC50/48h 24.9 mg/l (daphnia)

109-16-0 triethylen glycol dimethacrylate

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

· Persistence and degradability No further relevant information available.

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- · Behavior in environmental systems:
  - Bioaccumulative 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

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

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

14 Transport information		
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
· 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:	-	
· UN "Model Regulation":	Void	

# 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.

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- TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
- · Cancerogenity categories
  - · TLV (Threshold Limit Value established by ACGIH)

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

Α4

GHS label elements

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

Hazard pictograms



· 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

triethylen glycol dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Précautionary statements

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

Wear protective gloves.

If on skin: Wash with plenty of water. Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

· 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

H317 May cause an allergic skin reaction.

· Date of preparation / last revision 11/28/2017 / 2

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)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

Skin Sens. 1: Skin sensitisation - Category 1

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Skin Sens. 1B: Skin sensitisation – Category 1B

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