### **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

077032139

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

077029101 077029127 077029143 077029150 077029168 077029176 077029184 077029192 077029200 077029218 077029226 077029234 077032105 077032352 77032105 77032352

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).

077029135

Printing date 11/13/2007

Reviewed on 11/13/2007

#### 1 Identification of substance

- Product details
- · Trade name: Grandio
- · Application of the substance / the preparation Dental filling material
- Manufacturer/Supplier:

Voco GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

· Information department: Scientific department

· Emergency information: Scientific department tel. +49 (0) 4721 7190

#### 2 Composition/Data on components

- · Chemical characterization
- Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

1565-94-2 BIS-GMA

2.5-5%

### 3 Hazards identification

- · Hazard description: Not applicable.
- Information pertaining to particular dangers for man and environment:

The product does not have to be labelled due to the calculation procedure of international guidelines.

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

HMIS-ratings (scale 0 - 4)



0 Health = 0

Fire = 0

Reactivity = 0

#### 4 First aid measures

General information: No special measures required.

· After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult doctor.

### 5 Fire fighting measures

Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Protective equipment: No special measures required.

### 6 Accidental release measures

· Person-related safety precautions: Not required.

· Measures for environmental protection: No special measures required.

(Contd. on page 2)

Printing date 11/13/2007 Reviewed on 11/13/2007

Trade name: Grandio

· Measures for cleaning/collecting: Pick up mechanically.

Additional information: No dangerous substances are released.

(Contd. of page 1)

#### 7 Handling and storage

- Handling:
- Information for safe handling:

For dental use only.

No special measures required.

- Information about protection against explosions and fires: No special measures required.
- 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.

#### 8 Exposure controls and personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 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.
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands: Not required.
- · 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.

Eye protection: Not required.

#### 9 Physical and chemical properties · General Information Pasty Form: Color: According to product specification Characteristic Odor: Change in condition Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined. Not applicable. · Flash point: Product is not selfigniting. · Auto igniting: Product does not present an explosion hazard. Danger of explosion: Not determined. · Density: (Contd. on page 3)

Printing date 11/13/2007 Reviewed on 11/13/2007

Trade name: Grandio

(Contd. of page 2)

· Solubility in / Miscibility with

Water:

Not miscible or difficult to mix.

#### 10 Stability and reactivity

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Dangerous reactions No dangerous reactions known.
- Dangerous products of decomposition: No dangerous decomposition products known.

#### 11 Toxicological information

- · Acute toxicity:
- 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 internally approved calculation methods for preparations:

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.

#### 12 Ecological information

· General notes:

Water hazard class I (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

#### 13 Disposal considerations

- · Product:
- · Recommendation: Smaller quantities can be disposed of with household waste.
- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

#### 14 Transport information

DOT regulations:

· Hazard class:

- · Land transport ADR/RID (cross-border):
- · ADR/RID class:
- · Maritime transport IMDG:
- · IMDG Class:
- · Marine pollutant: No
- · Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -

- USA

(Contd. on page 4)

Printing date 11/13/2007 Reviewed on 11/13/2007

Trade name: Grandio

(Contd. of page 3)

# 15 Regulations

Sara

Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

Contact Voco for more informations

109-16-0 Triethylene glycol dimethacrylate

Proposition 65

Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity categories

EPA (Environmental Protection Agency)

None of the ingredients is listed.

IARC (International Agency for Research on Cancer)

Contact Voco for more information

NTP (National Toxicology Program)

Contact Voco for more informations

TLV (Threshold Limit Value established by ACGIH)

Contact Voco for more Information

· NIOSH-Ca (National Institute for Occupational Safety and Health)

Contact Voco for more information

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

#### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing MSDS: Scientific departement

Contact: Tel.: +49 (0) 4721 7190

-USA

Printing date 08/18/2021 Reviewed on 08/18/2021

#### 1 Identification

- · Product identifier
- · Trade name: Grandio
- · Application of the substance / the mixture Dental filling material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- · Information department: Scientific department tel. +49 (0)4721-719-0
- Emergency telephone number: Scientific department tel. +49 (0)4721-719-0

#### 2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.

*Under FDA regulations this product is classified as a medical device.* 

Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

· Classification of the substance or mixture



Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
- · Hazard pictograms



· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves / protective clothing.

If on skin: Wash with plenty of soap and water.

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

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

- · Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

### 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous compo		
CAS: 1565-94-2		2.5-5%
	💠 Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	
CAS: 109-16-0	Triethylene glycol dimethacrylate	<b>≤</b> 2.5%
	<b>♦</b> Skin Sens. 1, H317	
CAS: 72869-86-4	Urethanedimethacrylate	<b>≤</b> 2.5%
	💠 Skin Sens. 1B, H317	

US

Printing date 08/18/2021 Reviewed on 08/18/2021

Trade name: Grandio

(Contd. of page 1)

### 4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Seek medical treatment 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: 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.

### 5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: 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.

#### 6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections No dangerous substances are released.
- · Protective Action Criteria for Chemicals

· PAC-1:		
CAS: 109-16-0	Triethylene glycol dimethacrylate	$33 \text{ mg/m}^3$
CAS: 72869-86-4	Urethanedimethacrylate	120 mg/m³
· PAC-2:		
CAS: 109-16-0	Triethylene glycol dimethacrylate	$360 \text{ mg/m}^3$
CAS: 72869-86-4	Urethanedimethacrylate	$1,300 \text{ mg/m}^3$
· PAC-3:		
CAS: 109-16-0	Triethylene glycol dimethacrylate	$2,100 \text{ mg/m}^3$
CAS: 72869-86-4	Urethanedimethacrylate	$7,900 \text{ mg/m}^3$

# 7 Handling and storage

- · Handling:
- · Precautions for safe handling

For dental use only.

No special precautions are necessary if used correctly.

Observe the 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: See storage instructions on package

(Contd. on page 3)

Printing date 08/18/2021 Reviewed on 08/18/2021

Trade name: Grandio

(Contd. of page 2)

 $\cdot$  *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:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:



Protective gloves

· 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.

· Eye protection: Not required.

## 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty

Color: According to product specification

· Odor: Characteristic

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Auto igniting: Product is not selfigniting.

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

· **Density:** Not determined.

· Solubility in / Miscibility with

Water: Not miscible or difficult to mix.

· Viscosity:

**Dynamic:** Not determined. **Kinematic:** Not determined.

• *Other information* No further relevant information available.

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Printing date 08/18/2021 Reviewed on 08/18/2021

Trade name: Grandio

(Contd. of page 3)

### 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 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: No dangerous decomposition products known.

### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin:

Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured No irritant effect.

- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

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 (Internation	nal Agency for Research on Cancer)	
CAS: 13463-67-7	titanium dioxide	2B
CAS: 128-37-0	Butylated hydroxytoluene	3
· NTP (National To	oxicology Program)	
None of the ingrea	lients is listed.	
· OSHA-Ca (Occup	pational Safety & Health Administration)	
None of the ingrea	lients 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:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- $\cdot \textit{Additional ecological information:}$
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

Printing date 08/18/2021 Reviewed on 08/18/2021

Trade name: Grandio

(Contd. of page 4)

# 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.

4 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	s <b>II of</b> Not applicable.
· UN ''Model Regulation'':	Void

# 15 Regulatory information

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture} \\$
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

Glas Powder ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed

(Contd. on page 6)

Printing date 08/18/2021 Reviewed on 08/18/2021

Trade name: Grandio

(Contd. of page 5)

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed

- · Cancerogenity categories
- · EPA (Environmental Protection Agency)

None of the ingredients are listed

· TLV (Threshold Limit Value established by ACGIH)

Contact VOCO for more information.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed

#### 16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

- · Department issuing SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Date of preparation / last revision 08/18/2021 / 17
- · Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

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

-US