

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

Material Safety Data Sheet

acc. to ISO/DIS 11014

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)



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)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 11/13/2007

Reviewed on 11/13/2007

Trade name: Grandio

(Contd. of page 1)

- **Measures for cleaning/collecting:** Pick up mechanically.
- **Additional information:** No dangerous substances are released.

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 through 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

Form:	Pasty
Color:	According to product specification
Odor:	Characteristic

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.
-----------------	-----------------

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

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 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.

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)

Material Safety Data Sheet

acc. to ISO/DIS 11014

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

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.03.2015

Version number 16

Revision: 30.03.2015

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

- **1.1 Product identifier**
- **Trade name:** Grandio
- **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:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Further information obtainable from:** Scientific department tel. +49 (0)4721-719-0
- **1.4 Emergency telephone number:** Poison Control Center Mainz +49 (0)6131-19240

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**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** GHS07
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Wear protective gloves / protective clothing.
If skin irritation or rash occurs: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards** Use only for intended scope of application
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1565-94-2	BIS-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2,5-5%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene glycol dimethacrylate Skin Sens. 1, H317	≤ 2,5%

SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.03.2015

Version number 16

Revision: 30.03.2015

Trade name: Grandio

(Contd. of page 1)

- **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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
For dental use only.
No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** 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.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.03.2015

Version number 16

Revision: 30.03.2015

Trade name: Grandio

(Contd. of page 2)

- *Penetration time of glove material* Not applicable.
- *Eye protection:* Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Self-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.

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used 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: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.03.2015

Version number 16

Revision: 30.03.2015

Trade name: Grandio

(Contd. of page 3)

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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:**
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 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 II of MARPOL 73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

GB

(Contd. on page 5)

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

Printing date 30.03.2015

Version number 16

Revision: 30.03.2015

Trade name: Grandio

(Contd. of page 4)

SECTION 15: Regulatory information

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

SECTION 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 department

- **Contact:** Tel.: +49 (0)4721-719-0

- **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 Harmonized 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)

Skin Irrit. 2: Skin corrosion irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage eye irritation, Hazard Category 2

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

GB