

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

070413849

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

070413856 077032915 077032923 077032931 077032949 077033160 077033186 077033228 077033236 077033244  
077033251 077033269 077033277 077033285 077033293 077033301 077033319 077033327 077033335 077033343  
077033350 077033368 77033186 77033228 77033244 77033251 77033269 77033277 77033285 77033293 77033301  
77033319 77033327 77033335 77033343 77033350 77033368

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 08/16/2010

Reviewed on 08/16/2010

## 1 Identification of substance

- **Product details**
- **Trade name:** GrandioSo
- **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 tel. +49 (0)4721-719-0
- **Emergency information:** Scientific department tel. +49 (0)4721-719-0

## 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

- **Additional information:** Use only for intended scope of application

## 4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Seek medical treatment 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:**  
CO<sub>2</sub>, 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.

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**Trade name:** GrandioSo

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- **Measures for environmental protection:** No special measures required.
- **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.
  - **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** See storage instructions on package
  - **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:** Not required.
  - **Penetration time of glove material:** Not applicable.
  - **Eye protection:** Not required.

## 9 Physical and chemical properties

### · General Information

|               |                                    |
|---------------|------------------------------------|
| <b>Form:</b>  | Pasty                              |
| <b>Color:</b> | According to product specification |
| <b>Odor:</b>  | Characteristic                     |

### · Change in condition

|                                     |               |
|-------------------------------------|---------------|
| <b>Melting point/Melting range:</b> | Undetermined. |
| <b>Boiling point/Boiling range:</b> | Undetermined. |

|                     |                 |
|---------------------|-----------------|
| <b>Flash point:</b> | Not applicable. |
|---------------------|-----------------|

|                       |                              |
|-----------------------|------------------------------|
| <b>Auto igniting:</b> | Product is not selfigniting. |
|-----------------------|------------------------------|

|                             |   |
|-----------------------------|---|
| <b>Danger of explosion:</b> | Product does not present an explosion hazard. |
|-----------------------------|---|

|                 |                 |
|-----------------|-----------------|
| <b>Density:</b> | Not determined. |
|-----------------|-----------------|

|  |                                   |
|--|-----------------------------------|
| <b>Solubility in / Miscibility with<br/>Water:</b> | Not miscible or difficult to mix. |
|--|-----------------------------------|

## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

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Trade name: GrandioSo

- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** No dangerous decomposition products known.

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### 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

- **Information about elimination (persistence and degradability):** No datas available

### 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:** -

### 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
- **1565-94-2** | **BIS-GMA**

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**· 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)**

None of the ingredients is listed.

**· NTP (National Toxicology Program)**

None of the ingredients is listed.

**· TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

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

None of the ingredients is listed.

**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**· Canadian substance listings:****· Canadian Domestic Substances List (DSL)**

Contact Voco for more informations

**· Canadian Ingredient Disclosure list (limit 0.1%)**

Contact Voco for more informations

**· Canadian Ingredient Disclosure list (limit 1%)**

Contact Voco for more informations

**· 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)4721-719-0

USA

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 09/07/2016

## 1 Identification

- **Product identifier**
- **Trade name:** *GrandioSO*
- **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**  
The product is classified according to the Globally Harmonized System (GHS).



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

- **Label elements**
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **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 water.  
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 components:

|            |   |        |
|------------|---|--------|
| 1565-94-2  | BIS GMA<br>Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317 | 2.5-5% |
| 109-16-0   | Triethylene glycol dimethacrylate<br>Skin Sens. 1, H317                 | 2.5-5% |
| 41637-38-1 | BIS-EMA<br>Aquatic Chronic 4, H413                                      | 2.5-5% |

## 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

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**Trade name: GrandioSO**

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- **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:**  
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections** No dangerous substances are released.

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** For dental use only.
- **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:** See storage instructions on package
- **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:**  
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.

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Trade name: GrandioSO

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## · 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.

## 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.

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 09/07/2016

Trade name: GrandioSO

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## 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

##### · on the eye: No irritating effect.

#### · Sensitization: No sensitizing effects known.

#### · Additional toxicological information:

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)

|          |                            |   |
|----------|----------------------------|---|
|          | fumed silica               | 3 |
| 128-37-0 | 2,6-di-tert-butyl-p-cresol | 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: No further relevant information available.

#### · Persistence and degradability No datas available

#### · Behavior in environmental systems:

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

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

#### · 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: Smaller quantities can be disposed of with household waste.

### · 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

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# Safety Data Sheet

## acc. to OSHA HCS

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Reviewed on 09/07/2016

**Trade name: GrandioSO**

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

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

|  |
|--|
| · <b>Section 355 (extremely hazardous substances):</b> |
|--|

|                                     |
|-------------------------------------|
| None of the ingredients are listed. |
|-------------------------------------|

|  |
|--|
| · <b>Section 313 (Specific toxic chemical listings):</b> |
|--|

|                                     |
|-------------------------------------|
| None of the ingredients are listed. |
|-------------------------------------|

|   |
|---|
| · <b>TSCA (Toxic Substances Control Act):</b> |
|---|

|                             |
|-----------------------------|
| All ingredients are listed. |
|-----------------------------|

|                         |
|-------------------------|
| · <b>Proposition 65</b> |
|-------------------------|

|   |
|---|
| · <b>Chemicals known to cause cancer:</b> |
|---|

|                                     |
|-------------------------------------|
| None of the ingredients are listed. |
|-------------------------------------|

|  |
|--|
| · <b>Chemicals known to cause reproductive toxicity for females:</b> |
|--|

|                                    |
|------------------------------------|
| None of the ingredients are listed |
|------------------------------------|

|  |
|--|
| · <b>Chemicals known to cause reproductive toxicity for males:</b> |
|--|

|                                    |
|------------------------------------|
| None of the ingredients are listed |
|------------------------------------|

|   |
|---|
| · <b>Chemicals known to cause developmental toxicity:</b> |
|---|

|                                    |
|------------------------------------|
| None of the ingredients are listed |
|------------------------------------|

|                                     |
|-------------------------------------|
| · <b>Carcinogenicity categories</b> |
|-------------------------------------|

|  |
|--|
| · <b>EPA (Environmental Protection Agency)</b> |
|--|

|                                    |
|------------------------------------|
| None of the ingredients are listed |
|------------------------------------|

|   |
|---|
| · <b>TLV (Threshold Limit Value established by ACGIH)</b> |
|---|

|                                     |    |
|-------------------------------------|----|
| 128-37-0 2,6-di-tert-butyl-p-cresol | A4 |
|-------------------------------------|----|

|   |
|---|
| · <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b> |
|---|

|                                    |
|------------------------------------|
| None of the ingredients are listed |
|------------------------------------|

|                             |
|-----------------------------|
| · <b>GHS label elements</b> |
|-----------------------------|

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

|                                  |
|----------------------------------|
| · <b>Hazard pictograms GHS07</b> |
|----------------------------------|

|                              |
|------------------------------|
| · <b>Signal word</b> Warning |
|------------------------------|

|                            |
|----------------------------|
| · <b>Hazard statements</b> |
|----------------------------|

|                                      |
|--------------------------------------|
| May cause an allergic skin reaction. |
|--------------------------------------|

|                                   |
|-----------------------------------|
| · <b>Precautionary statements</b> |
|-----------------------------------|

|   |
|---|
| Wear protective gloves / protective clothing. |
|---|

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

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 09/07/2016

**Trade name: GrandioSO**

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*IF ON SKIN: Wash with plenty of water.**Dispose of contents/container in accordance with local/regional/national/international regulations.*

## 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** 09/07/2016 / 9

- **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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

US