

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

Printing date 01.06.2015

Version number 11

Revision: 28.04.2015

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

- **1.1 Product identifier**
- **Trade name: OMNIFILL C - powder**
- **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:**  
OMNIDENT Dental-  
Handelsgesellschaft mbH  
Gutenbergring 7-9  
D - 63110 Rodgau
- Tel.: +49 (6106) 8 74 - 0  
Fax: +49 (6106) 8 74 - 265  
Web: www.omnident.de
- **Further information obtainable from:** Productmanagement Tel.: +49 (6106) 8 74 - 0 (Mo.-Fr. 08:00 to 17:00)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.
- **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** Void
- **Hazard statements** Void
- **Precautionary statements**  
Wear protective clothing.
- **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:**

	fluoro-aluminosilicate glass	Eye Irrit. 2, H319	50-100%
	polyacrylic acid	Eye Irrit. 2, H319	5-10%
CAS: 87-69-4 EINECS: 201-766-0	(+)-tartaric acid	Eye Dam. 1, H318	2.5-5%

### 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.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

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**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **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**
- **Ingredients 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 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**

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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.

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

Form: Solid  
Colour: Beige  
Odour: Characteristic

· pH-value: Not applicable.

##### · 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:

Fully miscible.

##### · Viscosity:

Dynamic: Not applicable.  
Kinematic: Not applicable.

Solids content: 100.0 %

· 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

· on the eye: Irritating effect.

· Sensitization: Sensitization possible through skin contact.

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· **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.

**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**

Smaller quantities can be disposed of with household waste.

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.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**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 MARPOL73/78 and the IBC Code**

Not applicable.

· **UN "Model Regulation":**

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**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:** Productmanagement
- **Contact:** tel.: +49 (6106) 8 74 - 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)
  - Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
  - Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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- **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:**  
CO<sub>2</sub>, 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.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** For dental use only.
- **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**
- **Ingredients 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 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

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resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Eye protection:** Safety glasses

### **SECTION 9: Physical and chemical properties**

#### · **9.1 Information on basic physical and chemical properties**

##### · **General Information**

##### · **Appearance:**

· <b>Form:</b>	Fluid
· <b>Colour:</b>	Yellowish
· <b>Odour:</b>	Characteristic

· **pH-value:** Not determined.

##### · **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Self-igniting:** Product is not selfigniting.

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

· **Density at 20 °C:** 1.14 g/cm<sup>3</sup>

· **Solubility in / Miscibility with water:** Fully miscible.

##### · **Viscosity:**

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	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  
Irritant to skin and mucous membranes.

##### · **on the eye:** Irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

##### · **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

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Irritant

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**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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| <b>14.1 UN-Number</b>   |                 |
| · ADR, ADN, IMDG, IATA  | Void            |
| <b>14.2 UN proper shipping name</b>   |                 |
| · ADR, ADN, IMDG, IATA  | Void            |
| <b>14.3 Transport hazard class(es)</b>  |                 |
| · ADR, ADN, IMDG, IATA  |                 |
| · Class   | Void            |
| <b>14.4 Packing group</b>   |                 |
| · ADR, IMDG, IATA   | Void            |
| <b>14.5 Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>  | No              |
| <b>14.6 Special precautions for user</b>  | Not applicable. |
| <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| <b>UN "Model Regulation":</b>   | -               |

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**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.*

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  - 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)
  - Met. Corr.1: Corrosive to metals, Hazard Category 1
  - Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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