

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

Printing date 01.06.2015

Version number 15

Revision: 21.04.2015

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

- **1.1 Product identifier**
- **Trade name: OMNICERAM bulk fill SDC**
- **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**
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 IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of 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: 41637-38-1 EC number: 609-946-4	BIS-EMA	Aquatic Chronic 4, H413	10-25%
	aliphatic dimethacrylate	Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-25%

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.

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- **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.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **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.
- **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:**
Not required.



Protective gloves

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- **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.
- **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: Beige

· **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

· **on the eye:** No 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**

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 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)
 - 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
 - Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4

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