Printing date 03.06.2015

Version number 9

Revision: 23.04.2015

### SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier • Trade name: OMNITEMP C - base · 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 Temporary luting cement · 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: **OMNIDENT Dental-**Handelsgesellschaft mbH +49 (6106) 8 74 - 0 Tel.: Gutenbergring 7-9 Fax: +49 (6106) 8 74 - 265 D - 63110 Rodgau 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 Irrit. 2 H315 Causes skin irritation. Eye Irrit. 2 H319 Causes serious eye irritation. · 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 Causes skin irritation. Causes serious eye irritation. · Precautionary statements Wear protective gloves / eye protection. Wear 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 soap and water. · 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: coconut fatty acid 25-50% Skin Irrit. 2, H315; Eye Irrit. 2, H319 **SECTION 4:** First aid measures

· 4.1 Description of first aid measures

- · 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. If symptoms persist, consult a doctor.

• After swallowing: If symptoms persist consult doctor.

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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:

- 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: No special measures required.

· 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

· 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. Avoid contact with the eyes and skin.

• Protection of hands:



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

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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 an	d chemical properties
• 9.1 Information on basic physi	cal and chemical properties
· General Information	
· Appearance:	
Form:	Pasty
Colour:	Yellow-brown
· Odour:	Characteristic
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range	: 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:	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 Irritant to skin and mucous membranes.

• on the eye: Strong irritant with the danger of severe eye injury.

• Sensitization: No sensitizing effects known.

· 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: Generally not hazardous for water
- · 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.*

· 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 Anne	ex II of	
MARPOL73/78 and the IBC Code	Not applicable.	

# SECTION 15: Regulatory information

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

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### **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) MDC: Internetional Maritime Calo for Democracy Coode

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

Printing date 03.06.2015

Version number 8

Revision: 19.03.2009

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

· 1.1 Product identifier

· Trade name: OMNITEMP C - catalyst

 $\cdot$  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 Temporary luting cement

· 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

Eye Irrit. 2 H319 Causes serious eye irritation.

#### · 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
Causes serious eye irritation.
Precautionary statements
Wear protective gloves / eye protection.
Wear protective clothing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if prese

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 soap and water.
- · 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.

<ul> <li>Dangerous compone</li> </ul>	nts:	
	zinc oxide	10-25%
EINECS: 215-222-5	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
	calcium dihydroxide	2.5-5%
EINECS: 215-137-3	Eye Dam. 1, H318	
	Skin Irrit. 2, H315; STOT SE 3, H335	
	oleic acid, pure	$\leq 2.5\%$
EINECS: 204-007-1	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

#### **SECTION 4: First aid measures**

· 4.1 Description of first aid measures

· After inhalation: Seek medical treatment in case of complaints.

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Revision: 19.03.2009

Trade name: OMNITEMP C - catalyst

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- 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.

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

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GB

Printing date 03.06.2015

Version number 8

Revision: 19.03.2009

#### Trade name: OMNITEMP C - catalyst

#### · 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: Safety glasses

# SECTION 9: Physical and chemical properties

· 9.1 Information on basic physic	cal and chemical properties
· General Information	
· Appearance:	
Form:	Pasty
Colour:	Cream coloured
· 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:

· LD/LC50 values relevant for classification:

1314-13-2 zinc oxide

Oral | LD50 | > 5000 mg/kg (rat)

· Primary irritant effect:

• on the skin:

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

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#### Trade name: OMNITEMP C - catalyst

- on the eye: Irritating effect.
- Sensitization: No sensitizing effects known.

#### **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 product 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.*

· 14.1 UN-Number	
· ADR, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.

#### **SECTION 15: Regulatory information**

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

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Revision: 19.03.2009

Trade name: OMNITEMP C - catalyst

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#### **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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1 Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

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