Printing date 03.06.2015 Version number 6 Revision: 02.06.2015

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

· 1.1 Product identifier

· Trade name: OMNITEMP KB 4:1 - 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 Crown & Bridge 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. 1B 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 / 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 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:		
Polyesterdimethacrylate	Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-25%
Catalyst	Eye Dam. 1, H318 Acute Tox. 4, H302	2.5-5%
co-catalyst	Flam. Liq. 3, H226 Asp. Tox. 1, H304 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-2.5%

### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- $\cdot$  **After inhalation:** Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.

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· 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:

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: See storage instructions on package
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- $\cdot$  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.

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

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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: Safety glasses

## SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form:
Colour:
Colour:
Characteristic
Odour threshold:
Not determined.

Not determined.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

· Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.
Evaporation rate Not applicable.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Partition coefficient (n-octanol/water): Not determined.

· 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.

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• 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.
- · Additional toxicological information:

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

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6 Special procautions for user

Not applies blo

· 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'':

## 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

- · 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)

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

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

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

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Asp. Tox. 1: Aspiration hazard, Hazard Category 1

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Printing date 03.06.2015 Version number 7 Revision: 02.06.2015

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

- · 1.1 Product identifier
- · Trade name: OMNITEMP KB 4:1 Catalyst
- 1.2 Relevant identified uses of the substance or mixture and uses advised against Non-dental use.
- · Application of the substance / the mixture Temporary Crown & Bridge Material
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier: OMNIDENT Dental-

 Handelsgesellschaft mbH
 Tel.: +49 (6106) 8 74 - 0

 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 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 / eye protection.

Wear protective clothing.

If skin irritation occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

IF exposed or concerned: Call a POISON CENTER/doctor.

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:		
Polyesterdimethacrylate	Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-25%
benzoyl peroxyde	Org. Perox. B, H241 Eye Irrit. 2, H319; 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.

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Trade name: OMNITEMP KB 4:1 - Catalyst

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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:

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.
- 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: See storage instructions on package
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 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 resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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Trade name: OMNITEMP KB 4:1 - Catalyst

· Eye protection: Safety glasses

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### SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty
Colour: Whitish
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:

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

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Trade name: OMNITEMP KB 4:1 - Catalyst

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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.

SECTION 14: Transport information				
14.1 UN-Number				
IMDG, IATA	Void			
14.2 UN proper shipping name	-			
14.3 Transport hazard class(es)	-			
14.4 Packing group	-			
14.5 Environmental hazards:				
Marine pollutant:	No			
14.6 Special precautions for user	Not applicable.			
14.7 Transport in bulk according to Ann	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.

### SECTION 16: Other information

- · Department issuing MSDS: Productmanagement
- · Contact: Tel.: +49 (6106) 8 74 0
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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Version number 7 Printing date 03.06.2015 Revision: 02.06.2015

Trade name: OMNITEMP KB 4:1 - Catalyst

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)

Org. Perox. B: Organic Peroxides, Type B 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

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