Data sheet for medical devices / EU

Printing date 24.03.2025 Version number 1 Revision: 06.03.2025

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

· **1.1 Product identifier**

· **Trade name: Omnitemp KB - catalyst**
· **Chemical Identification:**
This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).
A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.
· **Product category** Dental medical device
· **Article category**
The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use.The instructions for use must be observed.
The product should only be applied by a professionally trained dental practitioner.
· **Application of the substance / the mixture** Temporary Crown & Bridge Material

· **1.3 Details of the supplier of the data sheet**
· **Manufacturer/Supplier:**
Manufacturer:
MP Medical Product GmbH
Grasweg 18-22
D – 27607 Geestland

Supplier:
OMNIDENT Dental-Handelsgesellschaft mbH
Gutenbergring 5
D – 63110 Rodgau

informing department:
Produktmanagement Tel. +49 (6106) 8 74 - 0

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).
The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment.The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

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Trade name: Omnitemp KB - catalyst

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· **Dangerous components:**	
Polyesterdimethacrylate Skin Sens. 1, H317	10-25%
benzoyl peroxide Org. Perox. C, H242; Aquatic Chronic 1, H410; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-1%

· **Additional information:**
Further information on ingredients can be found in the instructions for use.
In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

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.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **4.3 In case of contact with mucous membranes during treatment:** No special measures required.

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:** 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**
No special precautions are necessary if used correctly.
For use in dental application only.
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
· **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.

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· **Further information about storage conditions:**
Please observe the storage instructions on the packaging and in the instructions for use.

SECTION 8: Exposure controls/personal protection

· **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:**
Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

· **8.2 Exposure controls**
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	pasty
· **Colour:**	Whitish
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.

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· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.
· **10.2 Chemical stability** Stable.
· **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:**
Ensure that methacrylate-based linings and core build-ups (e.g. composites, compomers, ORMOCER®, resin-reinforced glass ionomer cement) are adequately insulated (e.g. with glycerine) to prevent the temporary restoration becoming bonded to the core build-up.
Phenolic substances, especially preparations containing eugenol and thymol, lead to curing disorders.The use of zinc oxide-eugenol cements or other eugenol-containing materials in combination with this product should be avoided.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **Other information**
As an invasive medical device, the product is subject to relevant laws and standards which ensure the safety and performance of the product when used appropriately and in accordance with the instructions for use. Specific toxicological information is not applicable at this point. The instructions for use must be observed.

SECTION 12: Ecological information

· **General notes:**
As an invasive medical device, the product is subject to relevant laws and standards that ensure the safety and performance of the product when used properly and in accordance with the instructions for use. Special environmental information is not applicable at this point. The instructions for use must be observed.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Dispose of in accordance with official regulations. For further information, see the instructions for use.

· **Uncleaned packaging:**
· **Recommendation:** Dispose of in accordance with official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	
· **ADR, IMDG, IATA**	Void

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Trade name: Omnitemp KB - catalyst

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· **14.3 Transport hazard class(es)**	
· **ADR, ADN, 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.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Regulation (EU) 2017/745
Medical Devices Regulation

Directive 93/42/EEC concerning medical devices
· **15.2 Chemical safety assessment:**
The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.
A Chemical Safety Assessment has not been carried out.

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.
The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

· **Relevant phrases**
H242 Heating may cause a fire.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing Datasheet:** Scientific department
· **Version number of previous version:** Not applicable.
· **Abbreviations and acronyms:**
Org. Perox. C: Organic peroxides – Type C/D
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Data sheet for medical devices / EU

Printing date 24.03.2025 Version number 1 Revision: 06.03.2025

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

· **1.1 Product identifier**

· **Trade name: Omnitemp KB - base**
· **Chemical Identification:**
This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).
A safety data sheet is not required by law for this product. This information is provided on a voluntary basis in the form of this Medical Devices Data Sheet.
· **Product category** Dental medical device
· **Article category**
The information relevant for the application and for the safety of users and patients is defined in the product-specific directions for use.The instructions for use must be observed.
The product should only be applied by a professionally trained dental practitioner.
· **Application of the substance / the mixture** Temporary Crown & Bridge Material

· **1.3 Details of the supplier of the data sheet**
· **Manufacturer/Supplier:**
Manufacturer:
MP Medical Product GmbH
Grasweg 18-22
D – 27607 Geestland

Supplier:
OMNIDENT Dental-Handelsgesellschaft mbH
Gutenbergring 5
D – 63110 Rodgau

informing department:
Produktmanagement Tel. +49 (6106) 8 74 - 0

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
This product is a medical device in accordance with Directive 93/42/EEC on medical devices or Regulation (EU) 2017/745 (MDR), which is used invasively or in contact with the body. It is therefore exempt from the classification and labelling requirements of Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d).
The classification criteria of Regulation (EC) No 1272/2008 are not directly applicable to this product, but are considered by us as an orienting basis for assessment.The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.The following hazards based on the classification criteria of Regulation (EC) No 1272/2008 for humans and the environment cannot be excluded:

Eye Dam. 1 H318 Causes serious eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)

Data sheet for medical devices / EU

Trade name: Omnitemp KB - base

(Contd. of page 1)

· **Dangerous components:**	
Polyesterdimethacrylate Skin Sens. 1, H317	10-25%
Catalyst Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	2.5-10%

· **Additional information:**
Further information on ingredients can be found in the instructions for use.
In case of known hypersensitivity to the ingredients mentioned in the instructions for use, do not use the product.

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.
· **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.
Rinse out mouth and then drink plenty of water.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **4.3 In case of contact with mucous membranes during treatment:** Remove excess immediately.

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:** 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**
No special precautions are necessary if used correctly.
For use in dental application only.
Observe the instructions for use! This contains the relevant application and safety information for the use of this product.
· **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.

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Data sheet for medical devices / EU

(Contd. of page 2)

· **Further information about storage conditions:**
Please observe the storage instructions on the packaging and in the instructions for use.

SECTION 8: Exposure controls/personal protection

· **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:**
Due to the proportions contained in relation to the amount of product during use and the way it is incorporated into the product, monitoring of specific, workplace-related limit values is not applicable.

· **8.2 Exposure controls**
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
In the context of the use of this product, the hygiene standards customary and general in dental practice, such as hand, mouth and eye protection, must be applied.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	pasty
· **Colour:**	Light brown
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Product is not selfigniting.

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Data sheet for medical devices / EU

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· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**
After mixing the base and catalyst paste, the product cures according to the product description and instructions for use.
· **10.2 Chemical stability** Stable.
· **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:**
Ensure that methacrylate-based linings and core build-ups (e.g. composites, compomers, ORMOCER®, resin-reinforced glass ionomer cement) are adequately insulated (e.g. with glycerine) to prevent the temporary restoration becoming bonded to the core build-up.
Phenolic substances, especially preparations containing eugenol and thymol, lead to curing disorders.The use of zinc oxide-eugenol cements or other eugenol-containing materials in combination with this product should be avoided.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **Other information**
As an invasive medical device, the product is subject to relevant laws and standards which ensure the safety and performance of the product when used appropriately and in accordance with the instructions for use. Specific toxicological information is not applicable at this point. The instructions for use must be observed.

SECTION 12: Ecological information

· **General notes:**
As an invasive medical device, the product is subject to relevant laws and standards that ensure the safety and performance of the product when used properly and in accordance with the instructions for use. Special environmental information is not applicable at this point. The instructions for use must be observed.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Dispose of in accordance with official regulations. For further information, see the instructions for use.

· **Uncleaned packaging:**
· **Recommendation:** Dispose of in accordance with official regulations.

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	
· **ADR, IMDG, IATA**	Void

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Data sheet for medical devices / EU

Trade name: Omnitemp KB - base

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· **14.3 Transport hazard class(es)**	
· **ADR, ADN, 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.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Regulation (EU) 2017/745
Medical Devices Regulation

Directive 93/42/EEC concerning medical devices
· **15.2 Chemical safety assessment:**
The health and environmental hazards have been assessed and classified on the basis of the information known to us on the components and their reaction processes.
A Chemical Safety Assessment has not been carried out.

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.
The product to which this data sheet is assigned is a medical device according to the EU Medical Devices Regulation EU 2017/745. Invasive medical devices or medical devices in direct physical contact are exempt from the requirements for classification and labelling according to Regulations (EC) 1907/2006 (REACH, Art. 2 (6) c)) and (EC) 1272/2008 ((UK) CLP, Article 1 (5) d). The Medical Devices Regulation does not require a safety data sheet for invasive medical devices or medical devices in direct body contact, as the safe use of the product is indicated in the instructions for use and/or the labelling. Nevertheless, we provide a data sheet for medical devices in order to provide as transparent a source as possible for the assessment of hazards to humans and the environment.

· **Relevant phrases**
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

· **Department issuing Datasheet:** Scientific department
· **Version number of previous version:** Not applicable.
· **Abbreviations and acronyms:**
Acute Tox. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3