

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

Review date 27.02.2027

SECTION 1 : PRODUCT AND COMPANY IDENTIFICATION

Product Name: Oratemp C&B
Intended use: Temporary Crown Material
Company Name: Prevest DenPro Limited
Address: Unit II, Export Promotion Industrial Park (EPIP), Bari Brahmana, Jammu (J&K)-181133 India
Tel: 0191 3506858 / 8899074151
Fax No: +91-1923-222774
Email: customercare@prevestdenpro.com
Web: www.prevestdenpro.com
Emergency Contact No: +91 8899074151

SECTION 2: HAZARD IDENTIFICATION

- **2.1 Classification of the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements**
H413 May cause long lasting harmful effects to aquatic life.
- **Precautionary statements**
P273 Avoid release to the environment.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3 : COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Chemical characterization: BASE

None of the components are hazardous

* SDS indicates the ingredient name and/or exact percentage is being withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

- **4.1 Description of first aid measures**
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Rinse with water.
- **After eye contact:**

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

Review date 27.02.2027

- 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 : FIRE FIGHTING 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 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**
Only adequately trained personnel should handle this product. For use in dentistry 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:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from heat and direct sunlight. Keep container tightly sealed.
- **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

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

Review date 27.02.2027

- **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:**
Usual hygienic measures for dental practice and dental laboratories. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** Not required.



The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

· 9.1 Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Paste
Colour:	white
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024
Version Number 1
Review date 27.02.2027

· Auto-ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits: Lower: Upper:	Not determined. Not determined.
· Vapour pressure:	Not determined.
· Relative density · Vapour density · Evaporation rate	Not determined. Not determined. Not determined.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
· 9.2 Other information	No further relevant information available.

SECTION 10 : STABILITY AND REACTIVITY

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **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** Keep away from heat and direct sunlight.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11 : TOXICOLOGICAL INFORMATION

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

MATERIAL SAFETY DATA SHEET

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Version Number 1
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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:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewagesystem.
- **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 INFORMATION

- **13.1 Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
Recommendation: Disposal must be made according to official regulations

SECTION 14 : TRANSPORT INFORMATION

· 14.1 UN-Number · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, 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 Marpol and the IBC Code	Not applicable.
· Transport/Additional information: transport	Product is not classified as a dangerous good for (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

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SECTION 15 : REGULATORY INFORMATION

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16 : OTHER INFORMATION *

Changes in content as per regulations – GHS classification

· **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 Harmonised 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)

PBT: Persistent, Bioaccumulative and Toxic vPvB:

very Persistent and very Bioaccumulative

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

- **Department issuing MSDS:** Regulatory affairs
- **SDS issue date:** 28.02.2024
- **Contact:** research @prevestdenpro.com

*Data compared to the previous version altered.

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Tel: 0191 3506858 / 8899074151
Fax No: +91-1923-222774
Email: customercare@prevestdenpro.com
Web: www.prevestdenpro.com
Emergency Contact No: +91 8899074151

SECTION 2: HAZARD IDENTIFICATION

- **Classification of the substance or mixture**
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3 : COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Chemical characterization:

CATALYST: None of the components are hazardous

* SDS indicates the ingredient name and/or exact percentage is being withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

- **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:** Rinse with water.
- **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.

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5 : FIRE FIGHTING MEASURES

Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture No further relevant information available.

Advice for firefighters

Protective equipment: No special measures required.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product. For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories. Wash hands before breaks and at

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024
Version Number 1
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the end of work. Keep away from foodstuffs, beverages and feed.

· **Respiratory protection:** Not required.

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

· **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 cannot be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

· Information on basic physical and chemical properties · General Information · Appearance: Form: Paste Colour: brown · Odour: Characteristic · Odour threshold: Not determined.	
· pH-value:	Not determined.
· Change in condition Melting point/freezing point: Undetermined. Initial boiling point and boiling range: Undetermined.	
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Auto-ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits: Lower: Upper:	Not determined. Not determined.

SECTION 10 : STABILITY AND REACTIVITY

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable under normal handling and storage conditions.

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

MATERIAL SAFETY DATA SHEET

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- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** Keep away from heat and direct sunlight.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11 : TOXICOLOGICAL INFORMATION

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitization** No sensitizing effects known.
- **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.
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:**
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 INFORMATION

- **13.1 Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
Recommendation: Disposal must be made according to official regulations

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SECTION 14 : TRANSPORT INFORMATION

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· 14.3 Transport hazard class(es) · ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, 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 Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

SECTION 15 : REGULATORY INFORMATION

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

SECTION 16 : OTHER INFORMATION *

Changes in content as per regulations – GHS classification

· **Relevant phrases**

H413 May cause long lasting harmful effects to aquatic life.

· **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)

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

MATERIAL SAFETY DATA SHEET

Date Issue 28.02.2024

Version Number 1

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vPvB: very Persistent and very Bioaccumulative

- **Department issuing MSDS:** Regulatory affairs
- **SDS issue date:** 28.02.2024
- **Contact:** research @prevestdenpro.com

*Data compared to the previous version altered.

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