

SECTION 1: IDENTIFICATION OF THE SUBSTANCE /MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier: Orthocem.

1.2 Recommended use and restrictions on use: Light curing orthodontic adhesive. Professional use only.

1.3 Supplier's details: Dentscare Ltda, Avenida Edgar Nelson Meister, 474, Joinville, Brasil.

1.4 Emergency telephone number: xx55 47 3441 6100.

SECTION 2: HAZARD IDENTIFICATION

2.1 Hazard classification: Irritant.

2.2 Label elements: Professional use only.



Irritant

2.3 Other hazards: The material is contraindicated if the person is allergic to any of the ingredients of the product .

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Chemical characterization: Mixture.

INGREDIENT:	CAS N. A:	CLASSIFICATION:	% CONCENTRATION:
Silane treated silicondioxide	248596-91-0	-	45- 60%
Bisphenol A Diglycidyl ether metacrylate (BisGMA)	1565-94-2	R36/37/38	25-35%
Triethyleneglycoldimethacrylate (TEGDMA)	109-16-0	R36/37/38	10-15%
Methacrylated phosphate monomer		R36/37/38	>2%
Sodium Fluorite	7681-49-4		>1%
Camphorquinone	465-29-2	R36/37/38	<1%

SECTION 4: FIRST AIND MEASURES

4.1 Description of first aid measures

4.1.1 Inhalation: Remove person to fresh air.

4.1.2 Skin contact: Wash with soap and water abundantly. If symptoms persist, seek medical assistance.

4.1.3 Eye contact: Wash with water abundantly. If symptoms persist, seek medical assistance.

4.1.4 Ingestion: If ingested, do not induce vomit. Seek medical assistance.

4.2 Most important symptoms and effects, both acute and delayed: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment required: Not applicable.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media: Use fire extinguishers with class B extinguishing agents (e.g., dry chemical, carbon dioxide).

5.2 Special hazards arising from the substance or mixture: Not applicable.

5.3 Special protective actions for fire-fighters: Wear full protective equipment and a self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.2 Environmental precautions: Non-defined.

6.3 Methods and material for containment and cleaning up: Clean up mechanically. Dispose of according to local and national regulations.

6.4 Reference to other sections: Non-defined.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling: Keep it away from high temperatures. Only adequately trained personnel should handle this product. Keep out of reach of children. Avoid eye contact. Avoid skin contact.

7.2 Conditions for safe storage including any incompatibilities: Keep the product in a cool place with the packing always well shut and protected. Avoid exposure to direct sunlight. Keep at temperatures of 5°- 30°C/ 41° – 86°F.

7.3 Specific end use(s): The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters: Not Applicable.

8.2 Exposure controls

8.2.1 Eye/face protection: Utilize protective glasses with side shields and mask.

8.2.2 Skin protection – hand protection: Gloves.

8.2.3 Skin protection - other: Utilize protective goggles.

8.2.4 Respiratory protection: Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

8.2.5 Thermal hazards: Not required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- a) **Appearance (form and colour):** Paste. Tooth colored.
- b) **Smell:** Slight acrylate odor.
- c) **Odour threshold:** No data available.
- d) **pH:** No data available.
- e) **Melting point/Melting range:** No data available.
- f) **Boiling point/Boiling range:** Not applicable.
- g) **Flash point:** Not Applicable.
- h) **Evaporation rate:** Not Applicable.
- i) **Flammability (solid, gaseous):** No data available.
- j) **Lower/upper explosion limit:** No data available.
- k) **Vapor pressure:** Not Applicable.
- l) **Vapor density:** Not Applicable.
- m) **Relative density:** No data available.
- n) **Solubility (s):** Not Applicable.
- o) **Partition coefficient: n-octanol/water:** Not Applicable.
- p) **Autoignition temperature:** Not Applicable.
- q) **Decomposition temperature:** Not Applicable.
- r) **Viscosity:** No data available.
- s) **Explosive properties:** Not Applicable.
- t) **Oxidising properties:** Not Applicable.

9.2 **Other information:** Not Applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1 **Reactivity:** Not Applicable.

10.2 **Chemical stability:** Stable.

10.3 **Possibility of hazardous reactions:** None.

10.4 **Conditions to avoid:** Exposure to blue or ultra-violet light and high temperatures causes the light curing of the product.

10.5 **Incompatible materials:** Not Applicable.

10.6 **Hazards decomposition products:** None, under normal conditions of storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 **Acute toxicity:** Oral - *Rattus norvegicus* - lineage Wistar – single dose: 2000mg / kg - 14 days. During the trial period, there was no mortality or any other symptoms among the animals tested. The product complies with the requirements of absence of toxicity.

11.1.2 Irritation: May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.

11.1.3 Corrosion: Not Applicable.

11.1.4 Sensitization: May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.

11.1.5 Repeated dose: Not Applicable.

11.1.6 Carcinogenicity: Not Applicable.

11.1.7 Mutagenicity: Not Applicable.

11.1.8 Reproductive toxicity: Not Applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: No data available.

12.2 Persistence and degradability: No data available.

12.3 Bioaccumulative potential: No data available.

12.4 Mobility in soil: No data available.

12.5 Results of PBT and vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods: In accordance with the governmental regulations of your country.

SECTION 14: TRANSPORT INFORMATION

14.1 UN-Number: Not Applicable.

14.2 UN proper shipping name: Not Applicable.

14.3 Transport hazard class(es): Not Applicable.

14.4 Packing group: Not Applicable.

14.5 Environmental hazards: Not Applicable.

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.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: These Material Safety Data were prepared according to Regulation (EC) N° 453/2010.

15.2 Chemical Safety Assessment: Not Applicable.

SECTION 16: OTHER INFORMATION

The information and recommendations are based on the MSDS and information of the raw material manufacturers.

Dentscare Ltda CNPJ 05.106.945/000106, is not responsible for the accuracy of this information or the need for additional information.