

ZirconiteTM Base CRPIS

1. Chemical Product and Company Identification

Product Name: Zirconite™, Base CRPIS

<u>Description:</u> Dual-cure adhesive resin cement for the permanent cementation of ceramic and zirconia restorations.

<u>Restrictions on use:</u> For use only by dental professionals.

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2. Hazards Identification

Acute Health Hazards: May cause eye, respiratory and skin irritation in high concentrations.



Chronic Health Hazards: Material is not known to cause significant health problems.

Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation.

Prolonged skin exposure can cause dryness.

Primary routes of exposure: inhalation, skin contact, eye contact

Carcinogenicity: NTP – no, OSHA – no, IARC – no.



3. Composition / Information on Ingredients

Hazardous Ingredients	% by Wt	CAS#	Hazard Identification & Risk Phrases
2-Hydroxyethylmethacrylate	<10%*	868-77-9	Xi, H319/315, H317
Triethyleneglycoldimethacrylate	<10%*	109-16-0	Xi, H319/335/315, H317
Copper (II) chloride dihydrate (3% aqueous solution)	<1%*	10125-13-0	Xn, N, H290, H312/302, H315, H318, H400, H411
10-methacryloyldodeylphosphonate	<10%*	85590-00-7	Xi, H319/335/315
Non-Hazardous Ingredients			
Photoinitiators	<5%*	10373-78-1	
Fumed Silica	<5%*	112945-52-5	
Bis-GMA	<20%*	1565-94-2	N/A
Glass Filler	<60%*	65997-17-3	N/A
Pigments White (TiO ₂) / Yellow**	<1%	13463-67-7/ Proprietary	N/A

^{*} The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

4. First Aid Measures

In case of inhalation: If irritation occurs, take victim to open air. If breathing difficulty persists, consult a physician.

In case of skin contact: Wash with soap and water.

In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.

In case of ingestion: Consult a physician.

5. Fire-Fighting Measures

Flash Point: N/E

Extinguishing Media: Carbon dioxide, water spray, dry chemical **Special Fire Fighting Procedures**: Avoid a direct jet of water.

Unusual Fire and Explosion Hazards: None

6. Accidental Release Measures

Environmental Precautions: Avoid seepage into sewers and water supplies.

Clean-Up Procedure: Contain spill and pick up material with a suitable absorbent material. Place absorbent into a container for later disposal. Clean spill area with detergent and water.

7. Handling and Storage

Handling: No special measures necessary if handled according to instructions.

Storage: Keep container tightly closed when not in use. Store in a cool, dry location. Keep material in original packaging.

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^{**} In Base shade White / Dentin only. Pigment is not present in Base Translucent shade formula.

^{✓ &}lt;u>Additional information:</u> For the wording of the listed risk phrases refer to section 16.



8. Exposure Controls / Personal Protection

Exposure Controls: Use only in well-ventilated areas.

Respiratory Protection: Avoid inhalation of vapors. No special protection under normal use. **Hand and Skin Protection**: Avoid unnecessary skin contact. Wear latex gloves when handling.

Eye Protection: Wear safety goggles or safety glasses with side shields when handling.

Hygiene Measures: Remove spilled material from skin and clothing. Do not eat or drink when handling

this material.

9. Physical and Chemical Properties

Appearance: White / Natural / Yellow paste

Odor: Specific odor

Boiling Point/Range: N/A

Evaporation Rate (Water = 1): N/A **Vapor Density** (Air = 1): N/A **Solubility in Water:** Insoluble

10. Stability and Reactivity

Stability: This material is stable.

Hazardous Reactions: None if handled according to directions

Hazardous Polymerization: May occur.

Conditions to Avoid: Heat, UV light and contamination.

Incompatibility: Free radicals, reducing agents, heavy metal ions

Hazardous Decomposition Products: Carbon dioxide, water, carbon monoxide, acrylic decomposition

products, depending on conditions of heating and burning.

11. Toxicological Information

Acute oral toxicity : LD_{50} (rat) > 5000mg/KG

Irritation of Skin: dryness and irritation possible upon prolonged exposure

Allergic Effects: Methacrylate sensitive individuals may exhibit an allergic reaction.

12. Ecological Information

Do not discharge into sewers or water supplies.

Environmental persistence and degradability: no data available

Ecotoxicity: no data available

13. Disposal Considerations:

May be disposed of in landfill or incinerator in accordance with local, state and federal regulations.

14. Transport Information:

14.1 Transport at land ADR RID

UN Number Kemler
Number

Packing Group

Proper shipping name

14.2 Transport at sea ADNR IMDG

UN Number

EMS MFAG

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Packing Group

Proper shipping name

ICAO / IATA-DGR

UN Number

Proper shipping name Subsidiary Risk

Labels

Packing Group

U.S. DOT Shipping Name: Not Regulated

U.S. DOT Hazard Class: None U.N./N.A. Number: None

U.S. DOT Packing Group: None **Other:** Not considered hazardous cargo

15. Regulatory Information:

14.3 Air transport

This product requires classification according to the criteria of EC.

The product is a medical device according to the Council Directive 93/42/EEC and EU Regulation 2017/745 for Medical Devices.

- 15.1 UN Number
- 15.2 National regulations
- 15.3 EU number
- 15.4 Hazard symbols



15.5 Hazard designation

Xi: Irritant.

15.6 Risk phrases

H: 319, 335/315, 317 319 Irritating to eyes.

335/315 Irritating to respiratory system and skin. 317 May cause sensitization by skin contact.

15.7 Safety phrases

P: 102, 403, 210, 260, 305+351+338, 303+361+353, 262,

280

102 Keep out of the reach of children.

403 Keep container in a well-ventilated place.

210 Keep away from sources of ignition - No smoking.

260 Do not breathe vapor.

305+351+338 In case of contact with eyes, rinse

immediately with plenty of water and seek medical advice. 303+361+353 After contact with skin, wash immediately

with plenty of water and soap.

262 Avoid contact with skin and eyes.

280 Wear suitable gloves and eye/face protection.



U.S.-O.S.H.A. Status: This material is not hazardous under the criteria of the U.S. Federal Hazard Communication Standard.

16. Other Information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

Relevant H-phrases

319/335/315 Irritating to eyes, respiratory system and skin. 317 May cause sensitization by skin contact.



Material should be maintained in original containers. Empty containers should not be re-used.

ANSI/NFPA 704 Data:

 $\begin{aligned} & \text{Fire} = 1 \\ & \text{Health} = 0 \\ & \text{Reactivity} = 0 \\ & \text{Specific Hazard} = \text{None} \end{aligned}$

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