

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

1.1- Product Identification

Product Name : Prime Cem Ceramic Reinforced
Product Description : Glass Ionomer Cement Restorative Cement.
Packing Available : 10ml Liquid and 15g Powder

1.2- Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Glass Ionomer Cement Restorative Cement. Used by dental professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacture : Prime Dental Products Pvt Ltd.
Address : Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane
(West)- 400604, Maharashtra, India
Email : info@prime-dental.in
Web : www.prime-dental.in

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

SECTION 2: Composition/information on ingredients

2.1- Mixture

| Component | C.A.S. | EINECS | Classification* | Weight% | LD50 |
|------------------|---------------|---------------|------------------------|----------------|---------------------------------------|
| Polyacrylic Acid | 9003-01-4 | NA | H314 | 30-99% | Not known |
| Distilled Water | 7732-18-5 | NA | NA | 30-99% | Not known |
| Tartaric acid | 87-69-4 | NA | H318 | 5-25% | Rat (Oral) – 2000 to 5000 mg/kg |

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : H314, H318

3.2- Information concerning to particular hazards to man and environment:

H314 Causes severe skin burns and eye damage

H318 Causes eye damage

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Contact with eyes: Flush eyes with plenty of water. Get medical attention, if irritation persists.

Ingestion: Give water. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention, if irritation persists.

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Depending on the materials involved in the fire.

5.2- Extinguishers not to be used: No information available

5.3- Risks arising from combustion: Formation of toxic gases is possible during heating or in case of fire.

5.4- Protective equipment: Use goggles in combination with dust mask, and another protections as appropriate to situation.

SECTION 6: Accidental Release Measures

- 6.1 Measures for personal safety:** Use goggles in combination with dust mask, and another protections as appropriate to situation.
- 6.2 Measures for environmental protection:** Do not discharge into the drains, surface waters or ground water directly
- 6.3 Measures for cleaning/collecting:** Absorb with liquid-binding material (sand, diatomite, sawdust). Ensure adequate ventilation.

SECTION 7: Handling and Storage

- 7.1- Handling product:** Is intended for dental use only.
- 7.2- Information for safe handling:** No special measures required. Observe normal care for working with chemicals.
- 7.3- Information about fire and explosion protection:** No special measures required.
- 7.4- Storage requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- 7.5- Information about storage in one common storage facility:** Not required.
- 7.6- Further information about storage conditions:** Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

- 8.1- Additional information about design of technical facilities:** No further data; see section 7.
- 8.2- Ingredients with limit values that require monitoring at the workplace:** No known
- 8.3- Personal protective equipment:**
- a. Respiratory protection** : Not required if room is well ventilated
 - b. 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.
 - c. Eye protection** : Safety glasses
 - d. Body protection** : Protective work clothing

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Liquid
Color : Clear
Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined
Boiling point/Boiling range : 101⁰C
Ignition temperature : Undetermined
Flash point : Undetermined
Self-igniting : Undetermined
Danger of explosion : Undetermined
Density : 1.2-1.4 mg/cm³

SECTION 10: Stability and Reactivity

- 10.1- Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications. Strong oxidants, acids, bases.
- 10.2- Dangerous reactions:** No dangerous reactions known
- 10.3 Dangerous decomposition products:** Carbon dioxide and monoxide

SECTION 11: Toxicological Information

- 11.1- Acute toxicity** : Not known
11.2- Primary irritant effect : Nil
11.3- On the skin : Not known
11.4- On the eye : May cause irritating effect.
11.5- Sensitization : No sensitizing effects known.
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SECTION 12: Ecological Information

12.1- Environmental data: Not known.

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

- 14.1- Air (ICAO/IATA)**
Primary Hazard Class/Division : Not Applicable
14.2- Road (RID/ADR)
Primary Hazard Class/Division : Not Applicable
14.3- Vessel (IMO/IMDG/RID/ADR)
Primary Hazard Class/Division : Not Applicable
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SECTION 15: Regulatory Information

15.1- Safety, health and environmental regulations/legislation specific for the substance or mixture
General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement:

H314 Causes severe skin burns and eye damage

H318 Causes eye damage

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

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SECTION 2: Composition/information on ingredients

2.1- Mixture

| Component | C.A.S. | EINECS | Classification* | Weight% | LD50 |
|-------------------------------|---------------|---------------|------------------------|----------------|-------------|
| Fluoro-alumino-silicate glass | NA | NA | NA | 85-100% | NA |
| Pigment | NA | NA | NA | <5% | NA |

*For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : NA

3.2- Information concerning to particular hazards to man and environment:

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Contact with eyes: Flush eyes with plenty of water. Get medical attention, if irritation persists.

Ingestion: Give water. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention, if irritation persists.

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Use extinguishing agent suitable for type of surrounding fire.

5.2- Extinguishers not to be used: Not known

5.3- Risks arising from combustion: No information available.

5.4- Protective equipment: Use goggles in combination with dust mask, and another protections as appropriate to situation

SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: Use goggles in combination with dust mask, and another protections as appropriate to situation

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water courses.

6.3 Measures for cleaning/collecting: Sweep or Vacuum to container. Ensure adequate ventilation.

SECTION 7: Handling and Storage

7.1-Handling product: Is intended for dental use only.

7.2- Information for safe handling: No special measures required. Observe normal care for working with chemicals.

7.3- Information about fire and explosion protection: No special measures required.

7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.

7.5- Information about storage in one common storage facility: Not required.

7.6- Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.

8.2- Ingredients with limit values that require monitoring at the workplace: No known

8.3- Personal protective equipment:

a. Respiratory protection : Not required if room is well ventilated

b. 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.

c. Eye protection : Safety glasses

d. Body protection : Protective work clothing

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Powder

Color : Off White

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : Undetermined

Self-igniting : Product is not self-igniting.

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

Density : Undetermined

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity : Not available

11.2- Primary irritant effect : Nil

11.3- On the skin : May cause skin irritation

11.4- On the eye : May cause irritating effect.

11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: No information available

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No classification

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : No classification

SECTION 15: Regulatory Information

15.1- Safety, health and environmental regulations/legislation specific for the substance or mixture

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement: Not available

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

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