Hema – GluTM Desensitizer with Fluoride

Hema-Glu™ SAFETY DATA SHEET

SECTION I - PRODUCT IDENTIFICATION

Company: Healthdent International Inc.

115 E. Ogden Ave. Suite 117-

322

Naperville, Illinois 60563

Phone: 1-800-845-5172

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SECTION II - HAZARD(S) IDENTIFICATION

OSHA Permissible Exposure Limits: None Other Exposure Limit Used: None

Used: None ACGIH Threshold Exposure Limit: None Chronic, Other: None

Acute Overexposure: Irritation to eyes and skin.

May cause chemical burn.

Medical Conditions Generally Aggravated by

Exposure: None

Known Hygienic Practices: None

Primary Route(s) of Exposure: Skin, eye, ingestion.

SECTION III - COMPOSITION/INFORMATION ON INGREDIENTS

 Material
 % WGT
 OSHA PEL
 ACGIH TLV

 Glutaraldehyde
 4-6%
 0.2 ppmv
 0.2 ppmv

 Hydroxylethyl
 Wathacrylate
 25-45
 NA
 NA

 Sodium Fluoride
 10 ppm
 NA
 NA

 Water
 Balance
 NA
 NA

(ND = Not Determined NA = Not Applicable NL = Not Listed)

FUNCTION

Stops dentinal fluid shifts by polymerization with proteins within the tubuli, providing a physiological seal.

SECTION IV - FIRST-AID MEASURES

Skin: Wash off affected area with soap and water. Ingestion: Seek immediate medical advice,

carry container with label.

Eyes: Rinse immediately with plenty of water

and seek medical advice.

SECTION V - FIRE-FIGHTING MEASURES

Flashpoint: >+ 104 °C

Extinguishing Media: Carbon Dioxide, Foam, Dry

Chemical

Special Fire Fighting Procedures: None

Flammable Limits: NA

Unusual Fire and Explosion Hazards: None

SECTION VI - ACCIDENTAL RELEASE MEASURES

Avoid contact with eyes, skin, and mucous membranes. If accidental contact occurs, FLUSH IMMEDIATELY WITH WATER. CONSULT PHYSICIAN IMMEDIATELY IF EYE CONTACT OCCURS. Keep away from children.

SECTION VII - HANDLING AND STORAGE

Spill Management: Use absorbent to collect the material. Wash contaminated surfaces with soap and water.

SECTION VIII - EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory: None required Eye Protection: Safety goggles Glove: Rubber/PVC gloves Other Clothing & Equipment: None Ventilation: None required

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure mm HG: NA Evaporation Rate (Ether = 1): NA Solubility in Water: Soluble Appearance: Clear Liquid

SECTION X - STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Prolonged Extreme Heat Incompatibility: (Materials to avoid) Contact with iron.

Hazardous Decomposition Products: None

Hazardous Polymeration: None

Conditions to Avoid: Extreme heat and free radical initiators.

SECTION XI - TOXICOLOGICAL INFORMATION

Acute Toxicity: ID oral rat. 2,000 mg/kg

Ames Test: Negative. Acrylates can cause sensitization reactions.

SECTION XII - ECOLOGICAL INFORMATION

Waste may be considered as inert material.

SECTION XIII - DISPOSAL CONSIDERATION

Dispose of safely in accordance with local, state, and federal regulations.

SECTION XIV - TRANSPORT INFORMATION

Stable under normal conditions of use, transportation, and storage.

SECTION XV - REGULATORY INFORMATION

510k # K951220

SECTION XVI - OTHER INFORMATION

WARNING! Glutaraldehyde based desensitizers will burn soft tissues. Keep off soft tissues. Avoid contact with eyes, skin, and mucous membranes. If accidental contact occurs, FLUSH IMMEDIATELY WITH WATER. CONSULT PHYSICIAN IMMEDIATELY IF EYE CONTACT OCCURS. Keep away from children.

The data and information given in this SDS are accurate on the date of preparation. It does not indicate any warranty or representation. We disclaim all liability relating to use of this material since this is beyond our control.

Healthdent International Inc.

115 E. Ogden Ave. Suite 117-322 Naperville, Illinois 60563 USA Phone 1-800-845-5172

Safety Data Sheet





INSTRUCTIONS

Hema-Glu [™] is a superior desensitizing agent, to be placed under dental cements or other restorative materials – temporary, provisional or final. Hema-Glu [™] can be used for desensitization of amalgam restorations, either conventional or bonded. Hema-Glu [™] helps kill bacteria, alter nerve responses and aids bonding primers in penetrating etched dentin.

GENERAL INFORMATION

Hema–Glu™ contains Glutaraldehyde and HEMA as well as a small amount of sodium fluoride as an added source of fluoride ion.

WITH GLASS IONOMER AND ZINC PHOSPHATE CEMENTS

Hema-Glu™ is very effective when applied to vital crown preparations prior to luting with these cements. It may also be used at the "prep" appointment to desensitize during temporization. When Hema-Glu™ is used properly in conjunction with these cements, complete desensitization will result in nearly all preparations.

WITH RESIN ADHESIVES

Most dentin bonding materials such as All Bond 2, Tenure, Optibond, Scotchbond MP, Photo Bond, etc. will benefit from $Hema-Glu^{TM}$ application. The application of

Hema-Glu[™] reliably reduces post-op sensitivity by supporting the collagen framework for easier penetration of the adhesive, thus enhancing the dentin bond.

WITH AMALGAMS

Hema–Glu[™] can be used to eliminate post-op sensitivity under standard amalgam restorations.

NON-BONDED RESTORATIONS

- 1. Clean tooth prep area.
- 2. Dry with air (dryness is not critical).
- 3. Apply **Hema**–**Glu**[™] to dried tooth using brush or cotton pellet. Avoid soft tissue.
- 4. Wait 30 seconds, then dry with air.
- Place restorative material such as amalgam, castings, etc. (Zinc phosphate and glass ionomer cements work well with Hema-Glu™.)

BONDED APPLICATIONS

- 1. Clean tooth prep area.
- 2. Etch with 10 40% phosphoric acid for 15 to 30 seconds.
- 3. Rinse.
- 4. Dry with air (dryness is not critical).
- Apply Hema–Glu[™], using brush or cotton pellet. Avoid soft tissue.
- Wait 30 seconds, then dry or leave moist, per manufacturer's instructions for the bonding agent.
- 7a. Direct restorations: Apply composite bonding agent and composite per manufacturer's instructions.
- 7b. Indirect restorations or sealing preparation: Apply composite bonding agent and luting resin per manufacturer's instructions.

Before and after Bleaching and Whitening/After root Planing/Perio treatment: Apply Desensitizer directly to the treated area with a gentle rubbing motion using a sterile cotton pellet.

STORAGE AND SHELF LIFE

Expiration date is placed on each **Hema–Glu**[™] bottle. **Hema–Glu**[™] has a three year shelf life when kept below 25^OC/77^OF.