

SECTION XII: ECOLOGICAL INFORMATION**Toxicity:**

Aquatic Toxicity: No further relevant information available.

Persistence and Degradability: No further relevant information available.

Behavior in Environmental Systems:

Bioaccumulative Potential: No further relevant information available.

Mobility in Soil: No further relevant information available.

General Information: Do not flush into surface water or sanitary sewer system.

SECTION XIII: DISPOSAL CONSIDERATIONS**Product:**

Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned Packaging:

Recommendation: Disposal must be made according to official regulations.

SECTION XIV: TRANSPORT INFORMATION**Land Transport ADR/RID**

and GGVS/GGVE (Germany): UN 1173 ETHYLACETAT, 3, II

Sea transport IMDG: UN 1173 ETHYLACETAT, 3, II

Air Transport ICAO-TI and IATA-DGR: UN 1173 ETHYLACETATE, 3, II

SECTION XV: REGULATORY INFORMATION

Classification According to EC-Guidelines: The product is a medical device according to EC-directive 93/42 EEC.

Chemical Safety Assessment: A Chemical Safety Assessment has not been carried out.

SECTION XVI: OTHER INFORMATION**Changes Compared With the Previous Version:**

Adaptation according to 1907/2006/EG, Article 31.

Prepared by: Peter G. Jordan

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data does not signify any warranty with regards to the product's properties. However, users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

**INSTRUCTIONS FOR USE**

Glisten Provisional Resin Glaze is a light-cure, one component varnish which cures hard, and without any smear layer. Glisten is for coating surfaces of temporary crowns or bridges based on acrylic and bisacrylic systems.

PROPERTIES:

The special properties of Glisten are its fully dry surface without leaving a smear layer after light polymerization, its hard, high gloss, and more abrasion-resistant surface.

The resistance of the covered crown and/or bridge will even be improved against solvation by some denture cleaning agents and against food deposits and plaque.

APPLICATION:

1. Remove the provisional material smear layer with a suitable solvent (e.g.: alcohol).
2. Apply a thin layer of Glisten without inclusion of air bubbles with a brush onto the dull and dry provisional restorative surface.
3. Light-cure the Glisten coating immediately after application:
 - Dental Halogen Light-Cure Unit (min. 500 mW/cm²): 20 sec.
 - LED Curing Light (min. 1000 mW/cm²): 40 sec.
4. If required, after light-curing, clean the surface with alcohol and water. The surface will shine with a high gloss.

Note: Close bottle immediately after use.

CONTRAINDICATIONS:

Glisten is free of methylmethacrylate. Do not use with patients with known allergies to methacrylates. In case of an allergic reaction, please contact a physician.

WARNINGS:

Glisten is flammable. Avoid sources of ignition and do not store in direct sunlight. In case of contact with oral tissue or skin, flush immediately with water. In case of contact with eyes, flush immediately with water and seek medical attention.

STORAGE:

Store Glisten protected from light. Do not store above 25°C/78°F. Do not use after expiry date.

**KEEP AWAY FROM CHILDREN.
FOR PROFESSIONAL USE ONLY.**

WARRANTY:

Clinician's Choice Dental Products warrants this product will be free from defects in material and manufacture. Clinician's Choice Dental Products makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for the user's application. If this product is defective within the warranty period, your exclusive remedy and Clinician's Choice Dental Products' sole obligation shall be repair or replacement of the product.

LIMIT OF LIABILITY:

Except where prohibited by law, Clinician's Choice Dental Products will not be liable for any loss or damage arising from this product – whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

For questions or comments, please call:

CLINICIAN'S CHOICE
DENTAL PRODUCTS INC.

167 Central Avenue, London, ON, Canada, N6A 1M6
For U.S. Distribution: Brookfield, CT, USA, 06804
1-800-265-3444 • Phone: (519) 641-3066



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SAFETY DATA SHEET

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

Trade Name: Glisten™ Provisional Resin Glaze

Use of the Preparation: Varnish

Details of the Supplier of the Safety Data Sheet:

 CLINICIAN'S CHOICE® Dental Products, Inc.,
167 Central Avenue, London, ON, Canada, N6A 1M6

For U.S. Distribution: Brookfield, CT, USA, 06804

Emergency Information: For emergencies or product information, please call 1-800-265-3444 (519-641-3066) (8:00am - 5:00pm EST)

Date of Issue: 20.05.2015

SECTION II: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Classification According to Regulation (EC) No 1272/2008:

Fam. Liq. 2, H225 Highly flammable liquid and vapor.

Eye Irrit. 2, H319 Causes serious eye irritation.

STOT SE 3, H336 May cause drowsiness or dizziness.

Information Concerning Particular Hazards for Human and Environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

LABEL ELEMENTS

Labeling According to Regulation (EC) 1272/2008:

Hazard Pictograms



Signal Word

Danger

Hazard Statements

H225 Highly flammable liquid and vapor

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

Precautionary Statements

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

Labeling According to EU Guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

OTHER HAZARDS

Results of PBT and vPvB Assessment

PBT: not applicable

vPvB: not applicable

SECTION III: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL CHARACTERIZATION:

Description of the Mixture: Light-cure varnish based on multifunctional methacrylates and ethylacetate.

Hazardous Components:

CAS-No. [141-78-6], EC-No. 2005-500-4 Ethylacetate GHS02, GHS07
H225, H319, H336

SECTION IV: FIRST-AID MEASURES

General Information: No special measures required.

After Skin Contact: Wash with plenty of water and soap.

After Inhalation: Fresh air.

After Eye Contact: Rinse opened eye for several minutes under running water and consult a doctor.

After Swallowing: Caution if victim vomits. Risk of aspiration. Keep airways free. Consult a physician. Subsequently administer: Activated charcoal (20 – 40 g in 10% slurry). Laxative: Sodium sulfate (1 tablespoon/ ¼L water).

SECTION V: FIRE-FIGHTING MEASURES

Extinguishing Media: CO₂, powder, water spray.

Use extinguishing method and media suitable to surrounding fire.

Special Hazards Arising From the Substance or Mixture: No further relevant information available.

Protective Equipment: Wear self-contained respiratory protective equipment.

SECTION VI: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

Do not inhale vapors/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

Environmental Precautions: Do not allow to enter drains/surface water/ground-water.

Methods for Cleaning Up: Absorb with liquid binding material. Clean up affected area.

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 VII: HANDLING & STORAGE

Handling: This product should only be supplied or handled by dentists or dental technicians or upon their instructions.

Precautions For Safe Handling: Observe normal care for working with chemicals.

Information About Fire and Explosion Protection: No special measures required.

Storage:

Requirements At Storerooms and Containers: Store only in the original containers.

Further Information on Storage Conditions: Store in well ventilated place at 15°C/59°F to 25°C/77°F, protected from light. Store away from food. Store tightly closed. Keep away from heat and sources of ignition.

Specific End Uses: No further relevant information available.

SECTION VIII: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components With Limits of Values to be Supervised at the Workplace:

| CAS-No. | name | art | value | unit |
|------------|--------------|---------|-------|-------------------|
| [141-78-6] | Ethylacetate | TRGS900 | 400 | ml/m ³ |
| | | or | 1500 | mg/m ³ |

Additional Information: The lists valid during the making were used as basis.

Personal Protective Equipment:

General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Keep away from food and beverages. Avoid contact with eyes or skin.

Hand Protection: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye Protection: Safety glasses

Respiratory Protection: Required, when aerosols are generated.

SECTION IX: PHYSICAL & CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form: Liquid

Color: Slightly yellow

Odor: Sweetish

| Safety Relevant Basic Data | value | unit | method |
|-------------------------------------|--|------|-----------|
| Melting Point/Melting Range: | n.a. | | |
| Boiling Point/Boiling Range: | approx. 77 | °C | |
| Flash Point: | -4 | °C | DIN 51755 |
| Ignition Temperature: | No information available | | |
| Danger of Explosion: | Lower limit of explosion 2.1 Vol% Kühn- Upper limit of explosion 11.5 Vol% Birett | | |

Density:

Vapor Pressure:

Solubility In/Miscibility With:

Water: Soluble

Content of Solvents:

Organic Solvents: Ethylacetate

SECTION X: STABILITY & REACTIVITY

THERMAL DECOMPOSITION/CONDITIONS TO BE AVOIDED

Possibility of Hazardous Reactions: no information available

Conditions to Avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

Hazardous Decomposition Products: No information available.

SECTION XI: TOXICOLOGICAL INFORMATION

Acute Toxicity: (ethylacetate)

LD50 (oral, rat) 5600 mg/kg

LD50 (dermal, rabbit) >18000 mg/kg

LD50 (inhal., rat) 5,86 mg/l (8h)

Primary Irritation:

Skin: Repeated exposure may cause skin dryness or cracking.

Eye: Strong irritating effect.

Inhalation and Swallowing: Irritation of mucous membranes, loss of appetite, headache, drowsiness.

Additional Toxicological Information: Allergic reactions to acrylates after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.