INSTRUCTIONS FOR USE

Dryz™ Gingival Hemostatic Retraction Paste

PRODUCT DESCRIPTION
Dryz™ Gingival Hemostatic Retraction Paste is a dental product capable of controlling gingival bleeding, temporarily displacing marginal gingiva and temporarily drying the gingival sulcus around a tooth. The paste allows the dental clinician to perform operative procedures without interference from moisture or hyperplastic soft tissue. Dryz is supplied in 0.5 ml syringes with hand plungers (packed in foil packages to prevent drying out), along with intra-oral tips to dispense the product into the gingival sulcus, instructions for use & MSDS.

INDICATIONS FOR USE
Dryz Gingival Hemostatic Retraction Paste is indicated for temporary retraction and hemostasis of the marginal gingival tissues during operative procedures such as subgingival and perigingival dental impressions, seating of fixed prostheses, and subgingival operative procedures.

CONTRAINDICATIONS FOR USE
Dryz Gingival Hemostatic Retraction Paste should not be swallowed, and is contraindicated for use on or by persons who are allergic to or sensitive to aluminum chloride, silicates or similar products. Symptoms may include dermatitis or inflammatory reactions. If this occurs, discontinue use and obtain medical care immediately. The product should not be used in the presence of active periodontal disease.

PRECAUTIONS FOR USE
Dryz should be used in non-infected gingival sulci above the level of the junctional epithelium. The dispensing tip should be held at the mouth of the sulcus, without actually entering down into it. The paste should be expressed slowly into the gingival sulcus, without actually entering down into it. The dispensing tip should be held at the mouth, to ensure no blockage exists in the tip. After the material has been in the sulcus for approximately 2 minutes, it must be completely removed. The sulcus should be thoroughly rinsed with water and inspected for residual material so none is left behind in the gingiva.

PRODUCT WARNINGS AND CLINICAL INFORMATION
- Store Dryz in a cool, dark place, unopened in the foil package prior to use.
- After opening, store the product with the original cap tightly screwed on in the resealable foil package to avoid drying out the material. Avoid sunlight or nearby heat sources. Shelf life will be reduced if not stored properly.
- The dispensing tips are single use only, and should be discarded after each use.
- Dryz Hemostatic Paste, like many agents used in dentistry to control bleeding, contains Aluminum Chloride, may cause corrosion on some plastic or metal surfaces (even stainless steel), if left on your instruments. To protect your dental instruments, always remember to rinse Dryz off of instrument surfaces immediately after each use.
- If product accidentally contacts skin, wash with copious amounts of water.
- If product accidentally contacts eyes, flush with water and obtain medical care immediately.
- Do not ingest this product, and keep it away from children.

GENERAL INSTRUCTIONS FOR USE
1) After tooth preparation is complete, rinse the sulcus with water. Dry with compressed air at an angle to the open sulcus, not directly into it.
2) Open the resealable foil package by tearing off the top where indicated. Save the bag for later storage. Remove the syringe from the package.
3) Dryz is a thick material being pushed through a thin needle tip. To ensure that the needle tip does not come off during placement, follow these steps before EACH use.
   a. Remove the sealing cap from the syringe. Save the cap, as it is used to reseal the syringe, if desired.
   b. Depress the plunger until Dryz is slightly extruding from the mouth of the syringe.
   c. Using the needle tip cover as a wrench, twist a needle tip onto the syringe until it is tight. If the tip is not fully locked on the syringe, it may come off when the plunger is squeezed.
   d. Remove the needle tip cover and bend the needle tip around a mirror handle to the desired angle, to prevent kinking. If the tip kinks, discard it and use another one.
   e. Bleed the syringe by slowly expressing a small amount of Dryz onto a pad outside of the mouth, to ensure no blockage exists in the tip.
   f. Express Dryz around the tooth into the mouth of the gingival sulcus, until it is slightly overfilled with material. Do not force the needle tip into the tissues. Allow the material to remain undisturbed in the sulcus for 2 minutes.
   g. To increase gingival retraction, pre-made cotton compression caps (or standard cotton rolls cut into short sections) may be placed over the tooth, followed by 2 minutes of blunting pressure by the patient’s opposing teeth.
   h. Dryz does not fully dry out in the sulcus. After 2 minutes, rinse it away with water and air and remove any remaining material using a non-cutting hand instrument or cotton pledget. Rinse and dry again. The sulcus is now ready for the impression.
4) Tips are for single-use on one patient only. Unbend the needle tip if necessary and remove it with the needle tip cover. Dispose of it in accordance with all applicable safety and environmental regulations. Each time the syringe is used, it must be with a new needle tip.
5) If any Dryz remains in the syringe, you may recap it with the original plastic cap (not a needle tip), and reseal it in the foil bag. The recapped syringe should be cleaned and disinfected with an EPA-registered low- (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant, as per the disinfectant manufacturer’s instructions. Consult the Centers for Disease Control website at CDC.gov, referencing the most recent version of the “Guidelines for Infection Control in Dental Health-Care Settings”. Store the syringe in the foil bag.
6) Alternately, the syringe may be discarded after a single use, in accordance with all applicable regulations.
7) If you have any questions, call 1-800-243-7446 or e-mail info@parkell.com.

WARRANTY:
Parkell will replace defective material for a period of one year from the date of manufacture. This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied. Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.

CONFORMANCE TO STANDARDS:
Parkell’s Quality System is certified to ISO 13485/9001. Material Safety Data Sheets are attached to these instructions, and can also be found at www.parkell.com

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European Authorized Representative
(Not a dealer/distributor):
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Molenstraat 15, 2513 BH, The Hague, The Netherlands
Tel: +31 (0)70 345 8570 • Fax: +31 (0)70 346 7299

Parkell, Inc.
300 Executive Drive, Edgewood, NY 11717
Toll-Free: 1-800-243-7448
Phone: 631-249-1134 • Fax: 631-249-1242
E-mail: info@parkell.com
www.parkell.com • Made in U.S.A.

STORE this product in a cool, dry place. Refrigeration will prolong shelf life, but avoid freezing. Bring to room temperature before use.
SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PARKELL, INC.
300A Executive Drive
Edgewood, NY 11717 USA

Company Telephone Number: (631) 249-1134
24-Hour Emergency Phone: InfoTrac 1-800-535-5053

PRODUCT NAME: Dryz Retraction Material

SECTION 2 – COMPOSITION INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>HAZARDOUS COMPONENTS</th>
<th>CAS NUMBER</th>
<th>PEL</th>
<th>TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum chloride hexahydrate</td>
<td>7784-13-6</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Other Ingredients</td>
<td></td>
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<tr>
<td>Filter and Cellulose Gum</td>
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SECTION 3 – HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: May cause eye, skin and respiratory irritation at high concentrations.

POTENTIAL HEALTH EFFECTS

EYES: May cause irritation.

SKIN: May cause irritation.

INHALATION: Prolonged or excessive inhalation may cause respiratory tract irritation.

INGESTION: May be harmful if significant quantity swallowed. Seek medical attention.

CHRONIC EFFECTS: None known.

SIGNS & SYMPTOMS:

Carcinogenicity: No NTP? No IARC MONOGRAPHS? No OSHA?

SECTION 4 – FIRST-AID MEASURES

INHALATION: Remove victim to fresh air. If irritation persists, contact physician.

EYES: Flush with plenty of water. Contact physician.

SKIN: Wash with soap and water.

INGESTION: Contact a physician if a substantial amount has been ingested. Do not induce vomiting.

SECTION 5 – FIRE-FIGHTING MEASURES

5.0 FLAMMABLE PROPERTIES: Non-flammable.
5.1 FLASH POINT: N/D
5.2 AUTOIGNITION TEMP: 
5.3 FLAMMABLE LIMIT: 
5.4 SUITABLE EXTINGUISHING MEDIA: Use dry chemical, carbon dioxide, or alcohol-resistant foam.
5.5 HAZARDOUS DECOMPOSITION PRODUCTS: Under fire conditions, hydrogen chloride gas and aluminum oxide may be formed.
5.6 SPECIAL PROTECTIVE EQUIPMENT: During emergency conditions, self-contained breathing apparatus should be worn.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution: Avoid skin/eye contact. Wear protective gloves.
6.2 Environmental precautions: Avoid ground water contamination.
6.3 Methods for cleaning-up: Wipe with damp paper towel.

SECTION 7 – HANDLING AND STORAGE

7.1 Handling: Observe normal warehouse handling procedures. Protect against physical damages.
7.2 Storage: Store in a cool, dry place.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 ENGINEERING CONTROLS: Use general and/or local exhaust to keep exposures to a minimum.
8.2 EYE/FACE PROTECTION: Use safety glasses. Eyewash station is recommended.
8.3 SKIN PROTECTION: Use protective gloves to prevent skin contact.
8.4 RESPIRATORY PROTECTION: None required during ordinary use of this product.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 APPEARANCE: Light colored paste.
9.2 ODOR: 9.3 pH: 9.4 VAPOR DENSITY (Air = 1):
9.5 BOILING POINT: 9.6 SOLUBILITY IN WATER: Not known
9.7 SPECIFIC GRAVITY (H2O = 1): @77°F (25°C)

SECTION 10 – STABILITY AND REACTIVITY

10.1 STABILITY: Stable.
10.2 CONDITIONS TO AVOID: Metal, acids.
10.3 INCOMPATIBILITY (MATERIALS TO AVOID): Strong metal, acids.
10.4 HAZARDOUS DECOMPOSITION PRODUCTS: Will not occur when using clinical amounts of this material.
10.5 HAZARDOUS POLYMERIZATION: 

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 HEALTH HAZARDS (IMMEDIATE, DELAYED, ACUTE, CHRONIC):
11.2 TOXICITY: For Aluminum Chloride Hexahydrate: LD50 Oral – rat – 3,311 mg/kg.
11.3 MUTAGENICITY: 
11.4 CARCINOGENICITY: No data available

SECTION 12 – ECOLOGICAL INFORMATION

12.1 GENERAL: Aluminum Chloride Hexahydrate: LC50 – other fish – 27.1 mg/l – 96h
12.2 MOBILITY: Readily absorbed into soil.
12.3 DEGRADABILITY: Biodegradable
12.4 ACCUMULATION: 
12.5 ECOTOXICITY: 
12.6 OTHER ADVERSE EFFECTS: Harmful to aquatic life.

SECTION 13 – DISPOSABLE CONSIDERATIONS

13.1 DANGER IN DISPOSAL: May be disposed of in landfill or incinerator. Consult federal, state and local regulations.

SECTION 14 – TRANSPORT INFORMATION (not meant to be all-inclusive)

14.1 PRECAUTIONS FOR TRANSPORT: NA – Not considered hazardous cargo
14.2 UN: 
14.3 IMDG: 
14.4 ICAO/IATA: 

SECTION 15 – REGULATORY INFORMATION (not meant to be all-inclusive)

15.1 RTECS: 
15.2 EU CLASSIFICATION: Xi : R36/37/38 (Irritating to eyes, respiratory system and skin)

SECTION 16 – OTHER INFORMATION

WORK/HYGIENIC PRACTICES: Wash hands after handling and before eating, drinking or smoking.

ANSI/NFPA Data: Fire = 0 Health = 1 Reactivity = 0

DATE PREPARED: 05/08/13
PREPARED BY: Parkell, Inc.

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