

# Caulk® 50% Tooth Conditioner Liquid

## DIRECTIONS FOR USE

**Caution:** U.S. federal law restricts this device to sale by or on the order of a dentist.

Caulk® 50% Tooth Conditioner Liquid is used in the acid etch procedure for treatment of enamel prior to placement of adhesive Pit and Fissure Sealant materials such as FluroShield® Pit and Fissure Sealant.

## COMPOSITION

Water, Phosphoric Acid

## INDICATION

Caulk® 50% Tooth Conditioner Liquid is used to surface condition intact or minimally instrumented enamel on primary and permanent teeth prior to adhesive pit and fissure material placement.

## CONTRAINDICATION

Caulk® 50% Tooth Conditioner Liquid is contraindicated for use on dental pulp tissue.

## WARNINGS

Caulk® 50% Tooth Conditioner Liquid contains 50% buffered phosphoric acid, which may cause burns. Avoid contact with oral tissues, eyes and skin. Do not take internally.

**Eye Contact:** Caulk® 50% Tooth Conditioner Liquid contains phosphoric acid, which may cause burns or may be irritating to eyes. Before using this product, wear protective glasses as well as covering the patient's eyes to protect from squirting the material inadvertently. In case of accidental contact with eyes, rinse eyes immediately with plenty of water and seek medical attention.

**Skin Contact:** Caulk® 50% Tooth Conditioner Liquid contains phosphoric acid, which can cause burns or skin sensitization in susceptible individuals. If contact with skin occurs immediately wipe off and flush with generous amounts of water, then wash well with soap and water after contact. If skin rash, irritation, sensitization or other allergic reaction occurs, seek medical attention immediately.

**Oral Mucosa Contact:** Avoid contact with oral soft tissues. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa persists, seek medical attention.

**Ingestion:** Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately. Contact regional Poison Control Center immediately.

## PRECAUTIONS

1. This product is intended to be used only as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
3. Contact with saliva and blood during sealant placement may cause failure of the sealant. Use of rubber dam or adequate isolation is recommended.
4. Replace original cap of Caulk® 50% Tooth Conditioner Liquid tightly after each use to avoid evaporation.
5. Insufficient data exist to support the use of Caulk® 50% Tooth Conditioner Liquid on dentin. Caulk® 34% Tooth Conditioner Gel is recommended for applications where dentin conditioning is desired.
6. The efficacy of Caulk® 50% Tooth Conditioning Liquid as an etchant/cleanser of indirect restorations has not been demonstrated.
7. Use only in well ventilated areas.
8. **Storage:** Store only in original container with tightly closed cap. Not to be stored at temperature exceeding 25°C. Do not freeze. Do not use after expiration date.

## ADVERSE REACTIONS

1. Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. (See Warnings)
2. Product may cause serious health effects if ingested. (See Warnings)

3. Product may cause pulpal effects. (See Contraindication)
4. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See Precautions)
5. The following medical conditions are generally aggravated by exposure: Individuals with pre-existing skin disorders, eye problems or impaired liver, kidney and respiratory functions.

## STEP-BY-STEP INSTRUCTIONS FOR USE

### 1. Cleaning

Clean uninstrumented enamel with a rubber cup and water/flour of pumice or a cleaning paste such as Zircate<sup>®</sup> Prophy Paste. Wash thoroughly with clean, oil-free water spray and air dry. Clean freshly instrumented enamel with water spray and then air dry.

### 2. Application of Caulk<sup>®</sup> 50% Tooth Conditioner Liquid

After application of rubber dam or other suitable isolation technique, apply Caulk<sup>®</sup> 50% Tooth Conditioner Liquid.

2.1 Place 2-3 drops of Caulk<sup>®</sup> 50% Tooth Conditioner Liquid into a clean well. Replace cap promptly.

2.2 Grasp a clean small cotton pellet using college pliers or other suitable instrument. Saturate the cotton by dipping into the liquid. Blot excess liquid against the inside of the well.

2.3 Apply Caulk<sup>®</sup> 50% Tooth Conditioner Liquid to enamel with the saturated small cotton pellet. For occlusal surfaces, condition the entire occlusal surface. For buccal and lingual pits and grooves, condition at least 2-3 mm of surrounding enamel. Avoid contact of the Caulk<sup>®</sup> 50% Tooth Conditioner Liquid with soft tissues (see Warnings).

2.4 Use a continuous slow and GENTLE wiping action for 60 seconds on permanent teeth and 90 seconds on deciduous teeth. Avoid excessive pressure that may destroy the retentive characteristics of the etched surface. A visible layer of conditioning solution should be present at all times during etching. Additional application of the conditioning solution may be required to maintain a visible layer for the required time. Do not allow conditioning solution to dry out on tooth surface.

2.5 After the appropriate contact time, remove liquid with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds. Dry conditioned enamel thoroughly with warm, oil-free air. Do not use alcohol or other agents to dry tooth. Properly conditioned and dried enamel will have dull (whitish) frosty appearance.

Properly conditioned surfaces must be kept free of contamination. If salivary contamination occurs, thoroughly clean with forceful water spray (free of oil contamination), blot dry and repeat conditioning procedure for 10 seconds, rinse as in step 4 above and dry as in step 5 above.

### 3. Application of Sealant

Proceed immediately to application of sealant per manufacturer's Directions for Use.

## DISINFECTION OF BOTTLE

To prevent Caulk<sup>®</sup> 50% Tooth Conditioner Liquid bottle from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. Repeated disinfection may damage label.

## LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
  - Reorder number
  - Lot number on the bottle
  - Expiration date

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