

**SECTION I - PRODUCT/ COMPANY IDENTIFICATION**

**REF 360116** Champ Pit & Fissure Sealant, 16 x 0.25ml

**REF 360120** Champ Pit & Fissure Sealant, 64 x 0.25ml

**Company:** CENTRIX, INC., 770 River Road, Shelton, CT 06484

Emergency / Information Telephone Numbers: 203-929-5582

Toll-Free: 800-235-5862 (USA & Canada)

**SECTION II - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION**

Classification: Irritant.

Adverse human health effects: May be irritating to eyes, respiratory system and skin.

May cause sensitization by skin contact.

**SECTION III - COMPOSITION**

Chemical characterization of the preparation: Acrylate ester monomers in a glass-filled, light-cured paste.

Hazardous ingredients

CAS NUMBER	NAME OF THE INGREDIENT	CONCENTRATION	WARNING SYMBOL,	R PHRASES
Proprietary	Uncured acrylate ester monomers	55-60%	Xi (Irritant),	R 36/37/38 - 43
112945-52-5	Silica, amorphous	5 %	Xi (Irritant),	R 36/37/38

**SECTION IV - FIRST AID MEASURES**

**General Information:** May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Avoid contact with eyes and skin. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

**Inhalation:** Move to fresh air. If necessary, administer oxygen and/or artificial respiration. Seek medical attention.

**Skin Contact:** Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.

**Eye Contact:** Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.

**Ingestion:** Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

**Precautions for first responders:** Ventilate the area. Wear eye and skin protection.

**Information for physicians**

**Symptoms:** Irritation or redness in eyes, throat or on skin.

**Hazards:** May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.

**Treatment:** As above under First Aid.

**SECTION V - FIRE-FIGHTING MEASURES**

Suitable extinguishing media: Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

Extinguishing media to avoid: Do not use direct water stream

Special exposure hazards in a fire: Heat may cause polymerization with rapid release of energy.

Special protective equipment for fire-fighters: A self-contained breathing apparatus should be worn by fire fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

**SECTION VI - ACCIDENTAL RELEASE MEASURES**

Personal precautions: Wear safety glasses, gloves and lab coat.

Environmental precautions: Avoid releasing large amounts of uncured material into the environment.

Cured / set-up material is, to our knowledge, inert.

Method for clean up: Contain spilled material. Absorb or wipe up spill with suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

**SECTION VII - HANDLING AND STORAGE**

**Handling:** For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Avoid direct / strong light sources, extremes of temperature, contamination, and cross contamination of two-part materials. Recap immediately after use.

**Storage:** Keep containers tightly closed. Store product in original container at cool room temperature (< 25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.

**Specific uses:** Dental material

**SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION**

Eye protection: None required Hands protection: None required

Engineering controls: None required Other equipment: None required

## SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Color / Physical state:

Natural tooth shade or off-white thin paste.

Odor: Faint, characteristic

Vapor pressure:< 1 mm Hg pH

Solubility in water: Nil

Specific gravity: 1.575

## SECTION X - STABILITY AND REACTIVITY

Conditions to avoid: Heat (> 38°C), light, contamination.

Materials to avoid: Reducing and oxidizing agents, peroxides, amines.

Hazardous decomposition products: Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Further information: Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

## SECTION XI - TOXICOLOGICAL INFORMATION

Acute toxicity: Not toxic. Minimal health hazard under normal conditions of use.

Local effects: Eye irritant, mucous membranes or skin on contact or with prolonged exposure. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.

## SECTION XII - ECOLOGICAL INFORMATION

Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.

## SECTION XIII - DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local regulations

## SECTION XIV - TRANSPORT INFORMATION

DOT- Not regulated

## SECTION XV - REGULATORY INFORMATION

Champ Pit and Fissure Sealant is a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC.

Hazard symbol: Xi

Hazardous ingredient: Uncured acrylate ester monomers

Risk phrases R36/37/38: Irritating to eyes, respiratory system and skin.

R43: Sensitizing by skin contact

Safety phrases: S24/25: Avoid contact with skin and eyes.

S3/9/49: Keep only in the original container in a cool, well ventilated place.

## SECTION XVI - OTHER INFORMATION

List of relevant R phrases: R36/37/38: Irritating to eyes, respiratory system and skin.

R43: Sensitizing by skin contact.

Training advice: Champ Pit and Fissure Sealant is for use by dental professionals only.

Restrictions on use: Champ Pit and Fissure Sealant is to be sold to and used by dental professionals only.

Further information: The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Centrix, Inc. bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. Sources of key data: National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law. Information which has been added, deleted or revised: This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) No. 1907/2006 (REACH).

**centrix**<sup>®</sup>

Making Dentistry Easier.<sup>SM</sup>

### CENTRIX INCORPORATED

770 River Road, Shelton, CT 06484 USA

(800) 235-5862 Tel: (203) 929-5582

Fax: (203) 929-6804



EC REP

### CENTRIX EUROPE

Hauptstrasse 64 B, 65719 Hofheim, Germany