

HOW SUPPLIED: Single Bottle

PROCEDURE FOR USE:

- 1) Clean tooth surface and remove plaque with a moistened cotton roll.

Note: For most effective desensitization, calculus accretions should be removed before applying Pain-Free F. This generally can be achieved without anesthesia by first applying Pain-Free F over the calculus...then gently scaling the surface...and finally reapplying Pain-Free F to the exposed dentin.

- 2) Dry the tooth surface by wiping with a fresh cotton roll.
- 3) Express two drops of Pain-Free F into a dappen dish.
- 4) Apply the Pain-Free F mixture to the sensitive surface with a cotton or foam pledget for 20-30 seconds. Use a rubbing/pumping motion to encourage the liquid to penetrate the surface. (If the pledget dries during application, re-wet it with more Pain-Free F.)
- 5) Dry with a gentle stream of air for 5 -10 seconds.

Test for sensitivity. If pain persists, repeat the application. If sensitivity persists after a second application, seriously consider other sources of pain (high occlusion, pulpal pathology, etc.)

STORAGE: Store Pain-Free F in a dark place at room temperature. Avoid extreme cold (below 32°F/0°C) and heat (126°F/50°C).

parkell*inc.*

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Caution: Federal Law restricts this device to sale by or on the order of a properly licensed practitioner



parkell*inc.*

INSTRUCTIONS FOR USE

PAIN-FREE™ F DESENSITIZER (S386)

MATERIAL DESCRIPTION: A tripolymer emulsion containing fluoride for treating non-pathological hypersensitivity.

INTENDED USE/INDICATIONS: To reduce sensitivity to thermal, mechanical or chemical stimuli due to patent dentinal tubules.

CONTRAINDICATIONS: Pain-Free F should not be applied to dentinal surfaces prior to bonding procedures. Pain-Free F seals the tooth so effectively that it prevents the dentin adhesive from reaching the dentinal surfaces. (If the surface is to be bonded, we suggest desensitizing it with Amalgambond® or Brush&Bond®.)

Not to be used if the patient suffers severe gingival inflammation. (Especially conditions which can lead to tissue sloughing, e.g., acute necrotizing ulcerative gingivitis (ANUG).)

PRECAUTIONS:

- **Do not refrigerate.** Cold temperatures will deactivate the emulsion.
- **Avoid eye contact.** If the material inadvertently gets into the eye, flush thoroughly with copious amounts of water. Contact a physician.
- **Immediately cease use if the soft tissue shows signs of irritation** (eg rash.)

ADVERSE EVENTS: None known.

CONFORMANCE TO STANDARDS:

Parkell's quality system is certified to ISO9001/ISO13485.

SEE OTHER SIDE
FOR MSDS SHEET

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SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PARKELL, INC.
300 Executive Drive
Edgewood, New York 11717

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

PRODUCT NAME: PAIN-FREE F

MSDS No: S381

CHEMICAL NAME: MS Polymer w/ oxalic acid

SECTION 2 – HAZARDS IDENTIFICATION

CLASSIFICATION ACC. TO DIRECTIVE 67/548/EEC:
 CLASSIFICATION ACC. TO REG. (EC) No. 1272/2008:

Xi: R36/38
 Eye Irritant 2, H319
 Skin Irritant 2, H315

LABEL ELEMENTS:
 Labeling Pictogram:



Signal Word: Warning
 Hazard Statements:
 H319 Causes serious eye irritation
 H315 Causes skin irritation

EMERGENCY OVERVIEW: May cause irritation.

POTENTIAL HEALTH EFFECTS

EYES: Contact with eyes may cause irritation and possible corneal injury.
 SKIN: Contact with skin may cause irritation.

INHALATION: May cause headache, dizziness, nausea, tinnitus or shock.
 INGESTION: May cause headache, dizziness, nausea, tinnitus or shock.

CHRONIC EFFECTS:

SIGNS & SYMPTOMS:

CARCINOGENECITY:

☐ No NTP?

☐ No IARC MONOGRAPHS?

☐ No OSHA?

SECTION 3 – COMPOSITION INFORMATION ON INGREDIENTS

HAZARDOUS COMPONENTS	CAS NUMBER	EC NUMBER	PEL	TLV	%
Polymer with sulfuric acid group/MS polymer	118571-13-4	N/A	NE	NE	
Oxalic Acid	6153-56-6	205-634-3	NE	NE	
Sodium Fluoride	7681-49-4	231-667-8	NE	NE	

SECTION 4 – FIRST-AID MEASURES

INHALATION:
 EYES: Immediately flush with flowing water for at least 15 minutes. Get medical attention.
 SKIN: Flush with soap and plenty of water. Get medical attention if irritation develops or persists.
 INGESTION: Give several glasses of water or milk to drink. Get medical attention.
 NOTE TO PHYSICIANS:

SECTION 5 – FIRE-FIGHTING MEASURES

FLASH POINT (TCC): Not flammable
 FLAMMABILITY CLASSIFICATION (NFPA 1910.1200):
 AUTOIGNITION TEMPERATURE: N/A
 EXTINGUISHING MEDIA: Use any means for extinguishing surrounding fire.
 FIRE FIGHTING INSTRUCTIONS: During emergency conditions, over-exposure to thermal decomposition products may cause health hazard. Self-contained breathing apparatus should be worn.
 UNUSUAL FIRE & EXPLOSION HAZARDS: None.
 HAZARDOUS COMBUSTION PRODUCTS: Toxic gases such as carbon monoxide may be release in a fire.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precaution: For skin protection, wear impervious protective gloves and clothing. For eye protection, use safety goggles or full face shield.
 Environmental Precautions: May be hazardous to the environment. Special attention should be given to water.
 Methods for cleaning-up: In case material is released or spilled, spread absorbent such as vermiculite or paper towel to absorb the material. Scoop up and place in a chemical waste container.

SECTION 7 – HANDLING AND STORAGE

HANDLING: Observe normal warehouse handling procedures. Protect against physical damage.
 STORAGE: Store in a cool, dry, dark, well-ventilated place. Store away from alkalis and direct sunlight. Do NOT store above 40°C.

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SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: Good general ventilation should be sufficient. Have eye wash station near work area.
 EYE/FACE PROTECTION: Use safety glasses.
 SKIN PROTECTION: Use impervious protective gloves to prevent skin contact.
 RESPIRATORY PROTECTION: None required during normal use of this product.
 EXPOSURE GUIDELINES: (oxalic acid) OSHA PEL 1mg/m³ (TWA) ACGIH TLV 2mg/m³ (STEL).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: Whitish, aqueous emulsion liquid. No odor.
 BOILING POINT: 100°C (water)
 VAPOR PRESSURE: Unknown
 VAPOR DENSITY (Air = 1): Unknown
 SOLUBILITY IN WATER: Miscible with water at any ratio.
 SPECIFIC GRAVITY (H₂O = 1):
 PERCENT VOLATILES:
 EVAPORATION RATE (Butyl Acetate = 1):
 PH:
 Approx. 1
 N/A
 Unknown
 Approx. 1

SECTION 10 – STABILITY AND REACTIVITY

STABILITY: Stable under ordinary conditions.
 CONDITIONS TO AVOID: Temperatures above 30°C and below 1°C. Direct sunlight.
 INCOMPATIBILITY (Materials to avoid): Metals such as silver, iron and calcium, and their compounds. Strong bases and strong oxidant.
 HAZARDOUS DECOMPOSITION PRODUCTS: Toxic gases such as carbon monoxide may be release in a fire.

SECTION 11 – TOXICOLOGICAL INFORMATION

For MS copolymer:
 Oral/mouse: LD50 >2000 mg/kg
 For oxalic acid:
 Oral/mouse: LD50 375 mg/kg
 Mutagenicity: Negative
 Carcinogenicity: (ACGIH) No (IARC) No.

SECTION 12 – ECOLOGICAL INFORMATION

GENERAL: This substance may be hazardous to the environment; special attention should be given to water.

SECTION 13 – DISPOSAL CONSIDERATIONS

Danger in Disposal: Should be handled as hazardous waste.
 Disposal Method: Waste must be disposed of in accordance with federal, state, and local environmental control regulations. Do not empty into sewer. Dilute with a large amount of water and send to waste water treatment facility.

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

PROPER SHIPPING NAME:
 DOT HAZARD LABEL: --
 DOT/UN CLASS: --
 IMDG CLASS: --
 UNNA NUMBER: --
 PACKING GROUP: --
 EmS: --

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

RISK STATEMENTS: R36/38 – Irritating to eyes and skin.
 HAZARD STATEMENTS: H319 Causes serious eye irritation
 H315 Causes skin irritation
 SAFETY STATEMENTS: S3 – Keep in a cool place.
 S7 – Keep container tightly closed.
 S9 – Keep container in a well-ventilated place.
 S20 – When using do not eat or drink.
 S29 – Do not empty into drains.
 S37/39 – Wear suitable gloves and eye/face protection.

SECTION 16 – OTHER INFORMATION

NFPA CODES: HEALTH - 2 FLAMMABILITY - 1 REACTIVITY - 1
 WORK/HYGIENIC PRACTICES: Wash hands before eating, drinking or smoking.

DATE PREPARED: 04/05/13 PREPARED BY: R. Burke

To the best of our knowledge, the information on this MSDS sheet is accurate. However, the information is provided without any warranty, expressed or implied, regarding its correctness or completeness. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This information is not warranted to be accurate whether originating with the company or not.