

Package Insert

PCxx
Neutral Foam

Contains: 2.0% Sodium Fluoride USP.

INDICATIONS: For topical application to aid in the protection against dental caries.

CLINICAL PHARMACOLOGY: Sodium Fluoride inhibits caries formation by reducing enamel solubility and enhancing remineralization.

CONTRAINdicATIONS: Hypersensitivity to Fluoride.

WARNINGS: Do not swallow. Accidental ingestion of the usual treatment dose (12mg fluoride) is not harmful. In case of larger doses use Ipecac Syrup emetic and immediately seek medical attention. 1 bottle of Neutral Foam contains 1.89 grams Fluoride Ion which could be lethal for a child.

PRECAUTIONS: For professional use only. Safety and effectiveness below age 3 have not been established.

Adverse Reactions: Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: Eczema, atopic dermatitis, urticaria, gastric distress, headache and weakness.

DOSAGE AND ADMINISTRATION:

- Slowly press down on pump.
- Dispense foam into applicator tray.
- Immediately place applicator tray in mouth. Do not fill applicator tray until ready to administer.
- Have patient bite down lightly but firmly for 4 minutes.
- Remove tray(s) and suction residual foam.
- Instruct patient not to eat, drink or rinse for at least 30 minutes.

SECTION 1 - PRODUCT IDENTIFICATION AND USE

PRODUCT IDENTIFIER: PCxx Neutral Foam Fluoride
PRODUCT IDENTIFICATION NUMBER: FL-FOAM-N
PRODUCT USE: TOPICAL FLUORIDE APPLICATION
PRODUCT MANUFACTURER: ROSS-EPS
EMERGENCY TELEPHONE NO.: 1-800-663-8303

SECTION 2 - HAZARDOUS INGREDIENTS

COMPONENT: SODIUM FLURIDE USP PERCENT: 2.0
CAS#7681-49-4
The human lethal dose of fluoride is 1 gram per 44 pounds of body weight.
ingestion of
as little as 30mg may produce symptoms in a small child. A container of
One Minute Foam contains 1.89 grams of Sodium fluoride.

SECTION 3 - PHYSICAL DATA

PHYSICAL STATE: WHITE FOAM SPECIFIC GRAVITY: 0.15
BOILING POINT: NOT DETERMINED SOLUBILITY: NOT DETERMINED

ODOR THRESHOLD: CHARACTERISTIC OF FLAVOUR VAPOR PRESSURE: AIR=1, 1.0

EVAPORATION RATE: NOT DETERMINED
FREEZING POINT: FREEZING POINT: -5°C, PRODUCT NOT AFFECTED BY FREEZING

pH: 7.0
VAPOUR DENSITY: NOT DETERMINED COEFF. WATER/OIL
DIST: NOT DETERMINED

SECTION 4 - FIRE AND EXPLOSION DATA

FIRE AND EXPLOSION: NOT FLAMMABLE
FLASH POINT: NOT DETERMINED, WATER BASED FORMULA
MEANS OF EXTINCTION: DRY CHEMICAL, CARBON DIOXIDE, WATER SPRAY OR
ALCOHOL RESISTANT FOAM
UPPER FLAMMABILITY LIMIT (%BY VOLUME): NOT DETERMINED
LOWER FLAMMABILITY LIMIT (%BY VOLUME): NOT DETERMINED
AUTOIGNITION TEMPERATURE: NOT AVAILABLEHAZARDOUS COMBUSTION
PRODUCTS:
SENSITIVITY TO IMPACT: NOT DETERMINED SENSITIVITY TO STATIC DISCHARGE:
NOT DETERMINED

SECTION 5 - REACTIVITY DATA

CHEMICAL STABILITY: STABLE
INCOMPATIBILITIES: AVOID EXTREME HEAT. AVOID SPRAYING TOWARDS OPEN
FLAME.
REACTIVITY: STRONG OXIDANTS
HAZARDOUS DECOMPOSITION PRODUCTS: NONE

SECTION 6 - TOXICOLOGICAL PROPERTIES

ROUTES OF ENTRY: INGESTION: YES, TOXIC EFFECTS OCCUR FROM
SWALLOWING EXCESSIVE AMOUNTS.
EFFECTS OF ACUTE EXPOSURE: ABDOMINAL PAIN, VOMITING, DIARRHEA, WEAKNESS
EFFECT OF CHRONIC EXPOSURE: CRIPPLING FLUOROSIS HAS BEEN OBSERVED WITH
DAILY INGESTION OF 10-25MF OF FLUORIDE OVER YEARS. DENTAL FLUOROSIS HAS
BEEN OBSERVED WHEN EXCESSIVE AMOUNTS ARE SWALLOWED BY CHILDREN
UNDER 7 YEARS OF AGE.
ACGIH THRESHOLD LIMIT VALUE: 2.5 mg(f)M³
OSHA PEL TWA: 2.5 mg(f)M³
8 HOUR TWA

SECTION 7 - PREVENTATIVE MEASURES

SECTION 8 - FIRST AID MEASURES

In case of larger doses use Ipecac Syrup emetic and immediately seek medical attention. 1
bottle of Neutral Foam contains 1.89 grams Fluoride Ion which could be lethal for a child.

SECTION 9 - PREPARATION OF MSDS

PREPARATION: TECHNICAL SERVICES PHONE: 1-800-663-8303

DATE: 1/1/2009