

10°C - 24°C / 50° F - 75°F



REF 360086C FluoroDose Mint, 120
REF 360087C FluoroDose Bubble Gum, 120
REF 360107C FluoroDose Melon, 120
REF 360110C FluoroDose Cherry, 120
REF 360137C FluoroDose Caramel, 120

REF 360078C FluoroDose Mint, 600
REF 360077C FluoroDose Bubble Gum, 600
REF 360108C FluoroDose Melon, 600
REF 360111C FluoroDose Cherry, 600
REF 360138C FluoroDose Caramel, 600

REF 360105C FluoroDose Mint, 1200
REF 360106C FluoroDose Bubble Gum, 1200
REF 360109C FluoroDose Melon, 1200
REF 360112C FluoroDose Cherry, 1200
REF 360139C FluoroDose Caramel, 1200

REF 870059C FluoroDose Bubble Gum, 8
REF 700001C FluoroDose Assorted, 40

Instructions for Use:

FluoroDose is a great-tasting, sodium fluoride varnish containing 50mg of sodium fluoride (equivalent to 22.6mg fluoride ion) per 1 mL. The convenient single-dose package allows easy mixing and application, for uniform results.

Directions for Use:

1. Clean teeth and remove excess moisture from area to be treated.
2. Grip the foil cover and slowly peel back, exposing the brush applicator and varnish well.
3. Remove applicator brush and stir material in well.
4. Paint a thin film of varnish onto treatment area.
5. Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
6. Dispose package and applicator after use.
7. Patient may leave immediately after treatment. Patient should be advised to remain on a soft food diet and only drink cold liquids for two hours after treatment; and not to brush for a minimum of 4 to 6 hours.
8. When dry, any excess varnish may appear "spotty" and may slide off the tooth surface. This will not affect the efficacy of the product as there is still a full layer of varnish on the tooth.

Contraindications:

1. Ulcerative gingivitis and stomatitis
2. Known allergic reactions to fluoride
3. Avoid ingestion during application
4. Known allergies to colophony or similar materials

Interactions:

Do not apply when other fluoride treatments (gels or foams) are to be done on the same day. The use of fluoride tablets and rinses should be interrupted for several days after initial treatment.

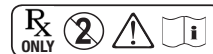
Adverse Reactions:

Edematous swellings have been reported in rare instances, especially after application to extensive surfaces. Dyspnea, although extremely rare, has occurred in asthmatic patients. Patients with sensitive stomachs have reported nausea on occasion. Varnish may easily be removed through tooth brushing and rinsing.

Non-Medical Ingredients:

Colophony, specially denatured alcohol F-38, beeswax, sucralose, green peppermint oil, derythrosine sodium, methylparaben

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NPN 80022634

REF 360086C FluoroDose Menthe, 120
REF 360087C FluoroDose Gomme à mâcher, 120
REF 360107C FluoroDose Melon, 120
REF 360110C FluoroDose Cerise, 120
REF 360137C FluoroDose Caramel, 120

REF 360078C FluoroDose Menthe, 600
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REF 360112C FluoroDose Cerise, 1200
REF 360139C FluoroDose Caramel, 1200

REF 870059C FluoroDose Gomme à mâcher, 8
REF 700001C FluoroDose, 40

Instructions pour application:

FluoroDose est un vernis de fluorure de sodium à goût savoureux. Il contient 50mg de fluorure de sodium (équivalent de 22.6 mg d'anion de fluorure) par 1mL. Un paquet-unité convenable permet un mélange et application faciles pour un résultat uniforme.

Administration :

1. Nettoyez les dents et enlevez l'excès d'humidité de la zone à être traitée.
2. Décollez lentement l'emballage en aluminium tout en exposant le pinceau applicateur et du vernis.
3. Enlevez le pinceau et bien mélangez le matériel.
4. Appliquez une couche mince de vernis sur la surface à être traitée.
5. Laissez le vernis sécher pendant environ 10 secondes puis demandez au patient de fermer la bouche.
6. Jetez l'emballage et l'applicateur après l'usage.
7. Le patient peut quitter immédiatement après le traitement. Il devrait être informé de suivre un régime alimentaire mou et de ne prendre que des liquides froids jusqu'à deux heures après le traitement. Il n'est non plus recommandé de se brosser les dents pendant un minimum de 4 à 6 heures.
8. Une fois sec, tout excès de vernis peut paraître "tacheté" et se détacher de la surface de la dent. Ceci n'affectera l'efficacité du produit puisqu'il y a toujours une couche complète de vernis sur la dent.

Contre-indications:

1. Gingivite ulcéraire ou stomatite.
2. Réactions allergiques au fluorure.
3. Réactions allergiques à la colophane ou d'autres produits similaires.
4. Évitez d'avaler le produit lors de son application.

Interactions:

Ne pas appliquer le produit lorsque d'autres traitements au fluorure (gel ou mousse) sont censés être administrés au cours de la même journée. La prise de comprimés et de rinçes au fluorure devraient être interrompue pour plusieurs jours à la suite du traitement initial.

Effets indésirables:

Des gonflements oedémateux ont été observés en cas rares, particulièrement lorsque le produit fut appliqué sur des surfaces étendues. Extrêmement rare, la dyspnée a été diagnostiquée chez des patients asthmatiques. Des nausées ont été observées, à l'occasion, chez les patients souffrant d'une sensibilité d'estomac. Le vernis peut être facilement enlevé lors du brossage et du rinçage des dents.

Ingrédients non médicinaux :

Colophane, alcool spécialement dénaturé F-38, cire d'abeille, sucralose, essence de menthe verte, sodium d'érythrosine, 2-hydroxybenzoate de méthyle.

SAFETY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

SECTION I - PRODUCT / COMPANY IDENTIFICATION

Product Name: FluoroDose®
Synonyms: Sodium Fluoride Cavity Varnish
Description: Colophony desensitizing dental varnish, tooth shade A2, in various flavors
Company Name: Centrix, Inc.
Address: 770 River Road
City, State, Zip: Shelton CT, 06484
Emergency Telephone Number: 203-929-5582
Information Telephone Number: 800-235-5862

SECTION II - HAZARD IDENTIFICATION

Designation of Risk: Xi, irritant
Special Details of Risk (R-categories): 36-38
Detrimental effects/symptoms: Irritant in case of eye, skin and inhalation contact.
Harmful if swallowed. Contact with acids liberates very toxic gas. May cause sensitization by skin contact.



SECTION III - COMPOSITION / INFORMATION ON INGREDIENTS

Preparation: rosin-based varnish in ethanol carrier with 5% sodium fluoride
Hazardous Ingredients:

Hazardous Components:

Name	CAS-No.	Content	Symbol	R-Categories
Rosin	8050-09-7	50-70%		R43 EINECS: 232-475-7
Ethanol	64-17-5	10-30%		[F] R11 EINECS: 200-578-6
Sodium Fluoride	7681-49-4	1-10%	Xi Xi	[T] R25; [-] R32; R36/38 EINECS: 231-667-8

Exact % content withheld due to trade secret restrictions.

SECTION IV - FIRST AID MEASURES

Symptoms Action

Skin contact: There may be mild irritation. Wash immediately with plenty of soap and water at the site of contact.
Eye contact: There may be irritation and redness. Bathe the eye with running water for 15 minutes.
Ingestion: There may be irritation of the throat. Wash out mouth with water.
Inhalation: No symptoms. Consult a doctor.

SECTION V - FIRE-FIGHTING MEASURES

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used.
Use water spray to cool containers.
Exposure hazards: In combustion emits toxic fumes.
Protection of fire-fighters: Wear self-contained breathing apparatus.
Wear protective clothing to prevent contact with skin and eyes.

SECTION VI - ACCIDENTAL RELEASE MEASURES

Personal Precautions: Avoid contact of skin or eyes. Wash hands with plenty of water.
Environmental Precautions: Do not let the material get in contact with sewerage systems.
Dispose in accordance with all federal, state, and local regulations.
Methods for Cleaning Up: Take up mechanically, use common absorbents.

SECTION VII - HANDLING AND STORAGE

Storage conditions: Store in cool, well-ventilated area. Keep container tightly closed.

SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazardous ingredients: ETHANOL
TWA 1920 mg/m³
Respiratory protection: Respiratory protection not required.
Hand protection: Protective gloves.
Eye protection: Safety glasses. Ensure eye bath is on hand.
Skin protection: Protective clothing.

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

State: Paste
Color: Off-white
Odor: Characteristic odor
Evaporation rate: Moderate
Solubility in water: Slightly soluble
Also soluble in: Ethanol.
Viscosity: Viscous
Other Data: Not available or none.

SECTION X - STABILITY AND REACTIVITY.

Stability: Stable under normal conditions.
Conditions to avoid: Heat.
Materials to avoid: Strong oxidizing agents. Strong acids.
Hazardous decomposition products: In combustion emits toxic fumes.

SECTION XI - TOXICOLOGICAL INFORMATION.

Exposure Route: Refer to section 4 of SDS for routes of exposure and corresponding symptoms.
LD50:
ETHANOL SODIUM FLUORIDE
IVN RAT LD50 1440 mg/kg ORL MUS LD50 57 mg/kg
ORL MUS LD50 3450 mg/kg ORL RAT LD50 52 mg/kg
ORL RAT LD50 7060 mg/kg SCU RAT LD50 175 mg/kg
NTP Listing: not a known or potential carcinogen

SECTION XII - ECOLOGICAL INFORMATION.

Mobility: Readily absorbed into soil.
Persistence and degradability: Biodegradable.
Bioaccumulative potential: No bioaccumulation potential.
Other adverse effects: Negligible ecotoxicity.

SECTION XIII - DISPOSAL CONSIDERATIONS.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

SECTION XIV - TRANSPORT INFORMATION.

ADR / RID UN no: -
Shipping Name: NOT CLASSIFIED AS DANGEROUS IN THE MEANING OF TRANSPORT REGULATIONS.
IMDG / IMO UN no: -
IATA / ICAO UN no: -

SECTION XV - REGULATORY INFORMATION

Hazard symbols: Harmful.
Risk phrases: R22: Harmful if swallowed.
R32: Contact with acids liberates very toxic gas.
R43: May cause sensitization by skin contact.
Safety phrases: S24: Avoid contact with skin.
S37: Wear suitable gloves.
PRECAUTIONARY PHRASES: Restricted to professional users.
Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

SECTION XVI - OTHER INFORMATION

Risk phrases used in s.2: R43: May cause sensitization by skin contact.
R11: Highly flammable.
R25: Toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R36/38: Irritating to eyes and skin.

CAUTION: The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility.



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