

SAFETY DATA SHEETS

This SDS packet was issued with item:

071896521

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070503524 70503524

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070451963 071896505 071896513 071896539 071896547 071896927

SECTION I - PRODUCT/ COMPANY IDENTIFICATION

Product Trade Name:

REF 360086 FluoroDose Mint, 120
REF 360107 FluoroDose Melon, 120
REF 360078 FluoroDose Mint, 600
REF 360108 FluoroDose Melon, 600
REF 360105 FluoroDose Bubble Mint, 1200
REF 360109 FluoroDose Melon, 1200

REF 360087 FluoroDose Bubble Gum, 120
REF 360110 FluoroDose Cherry, 120
REF 360077 FluoroDose Bubble Gum, 600
REF 360111 FluoroDose Cherry, 600
REF 360106 FluoroDose Bubble Gum, 1200
REF 360112 FluoroDose Cherry, 1200

CENTRIX, INC., 770 RIVER ROAD, SHELTON, CT 06484

Emergency Telephone Number: 800-235-5862

Information Telephone Number: 800-235-5862 203-929-5582

SECTION II - COMPOSITION/INFORMATION ON INGREDIENTS

Product Contents: Colophony Desensitizing Dental Varnish, Tooth Shade A2 - Bulk

Hazardous Ingredients:

Rosin 50-70%	EINECS: 232-475-7	CAS: 8050-09-7	[Sens.] R43
Ethanol 10-30%	EINECS: 200-578-6	CAS: 64-17-5	[F] R11
Sodium Fluoride 1-10%	EINECS: 231-667-8	CAS: 7681-49-4	[T] R25; [-] R32; [Xi] R36/38

SECTION III - HAZARDS IDENTIFICATION

Harmful if swallowed. Contact with acids liberates very toxic gas. May cause sensitisation by skin contact.

SECTION IV - FIRST AID MEASURES

Symptoms

Skin contact:

Action

There may be mild irritation at the site of contact.

Wash immediately with plenty of soap and water.

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: Refer to section 8 of SDS for personal protection details.

Turn leaking containers leak-side up to prevent the escape of liquid.

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

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 to hand.

Skin protection: Protective clothing.

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

State: Paste

Colour: Off-white

Odour: Characteristic odour

Evaporation rate: Moderate

Solubility in water: Slightly soluble

Also soluble in: Ethanol.

Viscosity: Viscous

SECTION X - STABILITY AND REACTIVITY

Stability: Stable under normal conditions.

Materials to avoid: Strong oxidising agents. Strong acids.

Conditions to avoid: Heat.

Haz. decomp. products: In combustion emits toxic fumes.

SECTION XI - TOXICOLOGICAL INFORMATION

Hazardous ingredients:

ETHANOL

IVN RAT LD50 1440 mg/kg

ORL MUS LD50 3450 mg/kg

ORL RAT LD50 7060 mg/kg

SODIUM FLUORIDE

ORL MUS LD50 57 mg/kg

ORL RAT LD50 52 mg/kg

SCU RAT LD50 175 mg/kg

Routes of exposure: Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

SECTION XII - ECOLOGICAL INFORMATION

Mobility: Readily absorbed into soil.

Bioaccumulative potential: No bioaccumulation potential.

Persistence and degradability: Biodegradable.

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 sensitisation 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 sensitisation 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.

Legal disclaimer:

CAUTION: PRODUCT FOR PROFESSIONAL USE ONLY.

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.

centrix®

Making Dentistry Easier.™

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CENTRIX EUROPE

Hauptstrasse 64 B, 65719 Hofheim, Germany

FluoroDose®

5% Sodium Fluoride Varnish with Xylitol

For printable Patient Take-Home Instructions visit: **centrixdental.com/takehome**

ENGLISH 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 LoliTray™ single dose package allows easy mixing and application for uniform results.

Directions for use:

- Clean teeth and remove excess moisture from area to be treated.
- Grip the foil cover and slowly peel back, exposing the brush applicator and varnish well.
- Remove applicator brush and stir material in well.
- Paint a thin film of varnish onto treatment area.
- Let the varnish dry for approximately 10 seconds and then instruct the patient to close their mouth.
- Dispose package and applicator after use.
- 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.
- 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:

- Ulcerative gingivitis and stomatitis
- Known allergic reactions to fluoride
- Avoid ingestion during application
- 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.

ITALIANO ISTRUZIONI PER L'USO

FluoroDose® Vernice a 5% fluoruro di sodio

Unicamente per uso professionale

Istruzioni per l'uso

FluoroDose è una vernice al fluororo di sodio dal gusto molto piacevole, contenente 50 mg di fluororo di sodio (equivalenti a 22,6 mg di ione fluororo) per ml. La comoda confezione monodose LoliTray™ permette una facile miscelazione e applicazione, per ottenere risultati uniformi.

Indicazioni per l'uso:

- Pulire i denti e rimuovere l'umidità in eccesso dall'area che deve essere trattata.
- Afferrare il rivestimento protettivo in alluminio e staccarlo lentamente, scoprendo bene il pennello applicatore e la vernice.
- Rimuovere il pennello applicatore e utilizzarlo per mescolare bene il materiale.
- Spennellare l'area da trattare con uno strato sottile di vernice.
- Lasciare asciugare la vernice per circa 10 secondi e poi chiedere al paziente di chiudere la bocca.
- Gettare la confezione e l'applicatore dopo l'uso.
- I pazienti possono andarsene subito dopo il trattamento. I pazienti dovrebbero consumare cibi morbidi e bere solamente bevande fredde per due ore dopo il trattamento, nonché di non spazzolare i denti per almeno 4-6 ore.
- Quando è asciutta, la vernice in eccesso può apparire “chiazzata” e può scivolare via dalla superficie del dente. Ciò non comprometterà in alcun modo l'efficacia del prodotto, perché sul dente vi è ancora uno strato completo di vernice.

Controindicazioni:

- Gingivite ulcerante e stomatite.
- Reazioni allergiche note al fluoro.
- Non ingerire durante l'applicazione.
- Allergie note alla colofonia o a materiali simili.

Interazioni:

Non applicare quando lo stesso giorno devono essere effettuati altri trattamenti a base di fluoro (gel o schiume). L'uso di compresse o collutori al fluoro dovrebbe essere interrotto per alcuni giorni dopo il trattamento iniziale.

Reazioni avverse:

In rari casi sono stati osservati rigonfiamenti edematosi, soprattutto in seguito ad applicazione su superfici estese. In pazienti asmatici si è verificata, molto raramente, dispnea. In pazienti con stomaco sensibile è stata riportata occasionalmente nausea. La vernice può essere facilmente rimossa spazzolando e sciacquando i denti.

REF 360086 FluoroDose Mint, 120

REF 360087 FluoroDose Bubble Gum, 120

REF 360107 FluoroDose Melon, 120

REF 360110 FluoroDose Cherry, 120

REF 360137 FluoroDose Caramel, 120

REF 360078 FluoroDose Mint, 600

REF 360077 FluoroDose Bubble Gum, 600

REF 360108 FluoroDose Melon, 600

REF 360111 FluoroDose Cherry, 600

REF 360138 FluoroDose Caramel, 600

FRANÇAIS MODE D'EMPLOI

FluoroDose® Vernis à 5% de fluorure de sodium

Réservé à l'usage professionnel

Utilisation:

FluoroDose est un vernis au fluorure de sodium au goût agréable contenant 50 mg de fluorure de sodium (équivalent à 22,6 mg d'ion de fluorure) par 1 ml. L'emballage à dose unique pratique LoliTray™ facilite le mélange et l'application pour des résultats uniformes.

Mode d'emploi:

- Nettoyer les dents et éliminer l'excédent d'humidité de la région à traiter.
- Saisir le film de protection et le tirer lentement pour mettre à nu la brosse applicatrice et le godet de vernis.
- Retirer la brosse applicatrice, la plonger dans le godet et mélanger.
- Appliquer un mince film de vernis sur la région à traiter.
- Laisser le vernis sécher pendant environ 10 secondes, puis dire au patient de fermer la bouche.
- Jeter l'emballage et l'applicateur après utilisation.
- Le patient peut partir immédiatement après le traitement. Conseiller au patient de manger des aliments mous et de boire des liquides froids seulement, pendant les deux heures qui suivent le traitement, ainsi que de ne pas se brosser les dents pendant 4 à 6 heures au minimum.
- Une fois sec, tout excédent de vernis peut prendre une apparence de « taches » et se détacher de la surface de la dent. Ceci n'affectera pas l'efficacité du produit, étant donné qu'une couche entière de vernis demeurera en place sur la dent.

Contre-indications:

- Gingivite ulcérateive et stomatite
- Réactions allergiques connues au fluorure
- Eviter l'ingestion pendant l'application
- Allergies connues à la colophane ou à des matières similaires

Interactions:

Ne pas appliquer lorsque d'autres traitements au fluorure (gels ou mousses) sont à effectuer le même jour. L'utilisation de comprimés et de rince-bouche au fluorure doit être interrompue pendant plusieurs jours après le traitement initial.

Effets indésirables:

Des gonflements oedémateux ont été rapportés dans des cas rares, tout spécialement après application sur des surfaces étendues. Une dyspnée, bien qu'extrêmement rare, est survenue chez des patients asthmatiques. Les patients à estomac sensible ont rapporté des nausées occasionnelles. Le vernis s'élimine facilement par brossage dentaire et rinçage.

ESPAÑOL INSTRUCCIONES DE USO

FluoroDose® Barniz 5% Fluoruro sódico

Uso exclusivo profesional

Instrucciones de uso

FluoroDose es un barniz de fluoruro sódico y excelente sabor que contiene 50mg de fluoruro sódico (equivalente a 22,6mg de ión fluór) por 1 ml. Su presentación en cómodos envases de dosis única LoliTray™ facilita su mezclado y aplicación, lográndose unos resultados uniformes.

Forma de administración:

- Limpie los dientes y retire el exceso de humedad del área a tratar.
- Suelte lentamente la película protectora, liberando el cepillo aplicador y el barniz.
- Retire el cepillo aplicador y mezcle el material.
- Aplique una capa fina de barniz sobre el área a tratar.
- Deje que se seque el barniz durante aproximadamente 10 segundos y seguidamente pídale al paciente que cierre la boca.
- Elimine el envase y el aplicador tras su uso.
- El paciente puede abandonar la consulta después del tratamiento. Se debe recomendar al paciente que coma alimentos blandos y sólo ingiera líquidos fríos en las dos horas siguientes al tratamiento, y que no se cepille los dientes durante las primeras 4 a 6 hs, como mínimo.

Una vez seco, cualquier exceso de barniz puede presentar un aspecto “irregular” y resbalar sobre la superficie dental. Esto no afectará a la eficacia del producto, dado que todavía queda una capa completa de barniz en el diente.

Contraindicaciones:

- Gingivitis ulcerativa y estomatitis.
- Reacción alérgica al fluoro.
- Evite su ingestión durante la aplicación.
- Hipersensibilidad a la colofonia o materiales similares.

Interacciones:

El producto no se debe aplicar si el mismo día se van a realizar otros tratamientos con fluororo (en forma de gel o espuma). Tras el tratamiento inicial, se deberá interrumpir el uso de enjuagues bucales y tabletas de fluororo durante varios días.

Efectos indeseables:

En casos excepcionales, se ha observado inflamación edematosa, especialmente después de una aplicación extensiva. En circunstancias poco frecuentes, pueden ocurrir disneas en pacientes asmáticos. En pacientes con estómagos sensibles se pueden producir, excepcionalmente, náuseas. El barniz se retira fácilmente mediante cepillado y enjuagado.

REF 360105 FluoroDose Mint, 1200

REF 360106 FluoroDose Bubble Gum, 1200

REF 360109 FluoroDose Melon, 1200

REF 360112 FluoroDose Cherry, 1200

REF 360139 FluoroDose Caramel, 1200

SUOMI KÄYTTÖOHJEET

FluoroDose® 5% natriumfluoridilakka

Vain ammattimaiseen käyttöön

Käyttöohjeet

FluoroDose on hyvänmakuinen natriumfluoridilakka, joka sisältää 50 mg natriumfluoridia (vastaa 22,6 mg fluoridi-onia) per 1 ml. Kätevä LoliTray™-yksittäispakkaus mahdollistaa helpon sekoituksen ja levityksen, jolloin tulos on yhdenmukainen.

Käyttöohjeet:

- Puhdista hampaat ja poista ylimääräinen kosteus käsiteltävältä alueelta.
- Tartu kalvoon ja vedä se hitaasti irti, jolloin applikaattoriharja ja lakkakuppi tulevat näkyviin.
- Poista applikaattoriharja ja sekoita kupissa oleva aine.
- Levitä ohut kerros lakkaa käsiteltävälle alueelle.
- Anna lakan kuivua noin 10 sekuntia ja pyydä sen jälkeen potilasta sulkemaan suu.
- Hävitä pakkaus ja applikaattori käytön jälkeen.
- Potilas saa lähteä kotiin heti käsittelyn jälkeen. On suositeltavaa, että potilas ei nauti kahteen tuntiin muuta kuin pehmeää ruokaa ja kylmiä juomia eikä harjaa hampaitaan 4–6 tuntiin.
- Kun lakka on kuivunut, ylimääräinen lakka saattaa näyttää ”läiskäiseltä” ja irrota hampaan pinnasta. Tämä ei heikennä aineen vaikutusta, sillä hampaan pinnalle jää kerros lakkaa.

Vasta-aiheet:

- Haavainen ientulehdus ja stomatitis
- Tunnetut allergiset reaktiot fluoridille
- Vältettävä nielemistä levittämisen aikana
- Tunnetut allergiset reaktiot kolofonille tai vastaaville aineille

Yhteisvaikutukset:

Ei saa käyttää, mikäli samana päivänä käytetään muita fluoridipitoisia aineita (geelejä tai vaahtoja). Fluoritablettien ja -huuhteluiden käyttö on keskeytettävä useaksi päiväksi käsittelyn tekemisen jälkeen.

Haittavaikutukset:

Turvotuksesta on raportoitu harvoissa tapauksissa, etenkin, kun tuotetta on levitetty suurille alueille. Hengenahdistusta on esiintynyt astmaattisilla potilailla, vaikkakin erittäin harvoin. Herkkävatsaisten potilaiden on raportoitu kärsineen pahoinvoinnista. Lakka on helppo poistaa harjaamalla hampaat ja huuhtomalla suu.

PORTUGUÊS INSTRUÇÕES DE UTILIZAÇÃO

FluoroDose® Verniz de fluoreto de sódio a 5%

Apenas para uso profissional

Instruções de utilização

FluoroDose é um verniz de fluoreto de sódio de paladar muito agradável, contendo 50 mg de fluoreto de sódio (equivalente a 22,6 mg de ião fluoreto) por 1 ml. A prática embalagem LoliTray™ de dose única permite uma mistura e aplicação fáceis, de modo a obter resultados uniformes.

Indicações de utilização:

- Limpar os dentes e remover o excesso de humidade da área a ser tratada.
- Levante o revestimento de alumínio e destaque-o lentamente, expondo a escova aplicadora e o reservatório de verniz.
- Remova a escova aplicadora e agite o material no reservatório.
- Aplique uma camada fina de verniz na área de tratamento.
- Deixe o verniz secar por cerca de 10 segundos e, depois, peça ao paciente para fechar a boca.
- Elimine a embalagem e o aplicador após a utilização.
- O paciente poderá ir-se embora imediatamente após o tratamento. O paciente deve ser aconselhando a manter uma dieta de alimentos moles e bebidas frias e a não escovar os dentes durante, no mínimo, 4 a 6 horas após o tratamento.

Quando seco, pode haver algum excesso de verniz (manchas) e escorrer da superfície do dente. Tal não afecta a eficácia do produto, dado que ainda permanece uma camada completa de verniz sobre o dente.

Contra-indicações:

- Gengivite e estomatite ulcerativas
- Reacções alérgicas conhecidas ao fluoreto
- Evitar a ingestão durante a aplicação
- Allergias conhecidas a colofonia ou materiais semelhantes

Interacções:

Não aplicar quando estão previstos outros tratamentos com fluoreto (em gel ou espuma) para o mesmo dia. Deve interromper-se o uso de comprimidos e elixires com fluoreto durante vários dias após o tratamento inicial.

Reacções adversas:

Foram notificadas tumefacções edematosas em circunstâncias raras, sobretudo após a aplicação em superfícies extensas. A dispneia, ainda que extremamente rara, ocorreu em pacientes asmáticos. Pacientes com o estômago sensível notificaram náusea ocasionalmente. O verniz pode ser facilmente retirado através de escovagem dos dentes e enxaguamento.

50°F -75°F / 10°C -24°C



DANSK BRUGSANVISNING

FluoroDose® 5% natriumfluoridlak

Kun til professionel brug

Brugsanvisning

FluoroDose er en velsmagende natriumfluoridlak, der indeholder 50 mg natriumfluorid (svarende til 22,6 mg fluoridion) pr. 1 ml. Den bekvemme LoliTray™ enkelt dosispakke muliggør nem blanding og applicering for at opnå ensartede resultater.

Brugsanvisning:

- Rengør tænderne, og fjern overskydende fugtighed fra det område, der skal behandles.
- Tag fat i folieovertrækket, og træk det langsomt tilbage, således at appliceringsbørsten og lakbrønden blotlægges.
- Fjern appliceringsbørsten og omrør materialet i brønden.
- Anbring en tynd film af lakken på behandlingsområdet.
- Lad lakken tørre i cirka 10 sekunder og bed derefter patienten lukke munden.
- Kasser pakken og appliceringsbørsten efter brug.
- Patienten kan gå umiddelbart efter behandlingen. Patienten skal rådes til at spise bløde fødevarer, kun drikke kold væske i to timer efter behandlingen og undlade at børste tænderne i mindst 4 - 6 timer.
- Når lakken er tør, kan der "pletvis" forekomme overskydende lak, som glider af tandoverfladen. Det forringer ikke effekten af produktet, da der stadig er et fuldstændigt lag lak på tanden.

Contraindikationer:

- Ulcerativ gingivitis og stomatitis
- Kendte allergiske reaktioner over for fluorid
- Undgå synkning under applicering
- Kendte allergier over for kolofonium eller lignende materialer

Interaktioner:

Bør ikke appliceres, når andre fluoridbehandlinger (gel eller skum) skal foretages på samme dag. Brugen af fluoridtabletter og -skyninger bør afbrydes i flere dage efter den første behandling.

Bivirkninger:

I sjældne tilfælde er der rapporteret ødematøse hævelser, særligt efter applicering på store overflader. Der er blevet konstateret dyspnø hos astmapatienter, selvom det kun forekom i yderst sjældne tilfælde. Patienter med følsom mave har lejlighedsvis klaget over kvalme. Lakken kan let fjernes vedat pudse tænder og skylle munden med vand.

NEDERLANDS GEBRUIKSAANWIJZING

FluoroDose® Vernis met 5% natriumfluoride

Alleen voor professioneel gebruik

Gebruiksaanwijzing

FluoroDose is een goed smakende natriumfluoridevernis met 50 mg natriumfluoride (dat komt overeen met 22,6 mg fluoride-ionen) per ml. De handige LoliTray™-ééndosisverpakking maakt mengen en aanbrengen gemakkelijk, zodat u uniforme resultaten behaalt.

Het gebruik:

- Maak de tanden schoon en verwijder overtollig vocht van het te behandelen gebied.
- Pak de afdekfolie vast en trek deze langzaam van de verpakking, zodat de aanbrengborstel en de mengcup bloot komen te liggen.
- Verwijder de aanbrengborstel en roer het materiaal in de mengcup.
- Breng een dunne laag vernis aan op het te behandelen gebied.
- Laat het vernis gedurende ongeveer 10 seconden drogen en geef de patiënt vervolgens opdracht zijn/haar mond te sluiten.
- Werp de verpakking en de aanbrengborstel na gebruik weg.
- De patiënt kan onmiddellijk na de behandeling naar huis. Wel moet de patiënt worden aanbevolen gedurende twee uur na de behandeling alleen zacht voedsel te eten en alleen koude dranken te drinken en af te zien van tandenpoetsen gedurende minimaal de eerste 4 tot 6 uur.
- Als het vernis droog is, kan een eventueel teveel "vlekkerig" lijken en van het tandoppervlak glijden. Dit heeft geen invloed op de werkzaamheid van het product, omdat er nog een volledige laag vernis op de tand zit.

Contra-indicates:

- Ulceratieve gingivitis en stomatitis.
- Bekende allergische reacties op fluoride.
- Voorkom dat het vernis bij de behandeling wordt doorgeslikt.
- Bekende allergieën voor colofonie of dergelijke materialen.

Interactie:

Niet gebruiken als op dezelfde dag ook andere fluoridebehandelingen (met een gel of een schuim) moeten worden uitgevoerd. Het gebruik van fluoridetabletten en fluoridespoelingen moet na de eerste behandeling voor enkele dagen worden gestaakt.

Bijwerkingen:

Edemateuze zwellingen zijn in zeldzame gevallen gerapporteerd, vooral na het aanbrengen van fluoridevernis op grote gebieden. Dyspnea is uiterst zeldzaam maar kan bij astmatische patiënten optreden. Patiënten met een gevoelige maag worden soms licht misselijk. Het vernis kan door middel van tandenpoetsen en spoelen gemakkelijk worden verwijderd.

DEUTSCH GEBRAUCHSANWEISUNGEN

FluoroDose® Lack mit 5% Natriumfluorid
Nur zur zahnärztlichen Verwendung

Gebrauchsanweisungen

FluoroDose ist ein besonders angenehm schmeckender Natriumfluoridlack, der 50 mg Natriumfluorid je 1 ml enthält (das entspricht 22,6 mg Fluoridionen). Der praktische LoliTray™ Einweg-Pack ermöglicht ein einfaches Mischen und Auftragen, damit gleichmäßige Ergebnisse erzielt werden.

Verarbeitungsanleitung:

1. Zähne reinigen und überschüssige Feuchtigkeit aus dem zu behandelnden Bereich entfernen.
2. Folieabdeckung anfassen und langsam nach hinten ziehen, so dass der Applikator-Pinsel und das Behältnis mit dem Lack frei liegen.
3. Applikator-Pinsel entfernen und Material im Behältnis umrühren.
4. Einen dünnen Film Lack auf den Behandlungsbereich auftragen.
5. Den Lack etwa 10 Sekunden lang trocknen lassen und den Patienten anweisen, den Mund zu schließen.
6. Packung und Applikator nach Gebrauch entsorgen.
7. Der Patient kann nach der Behandlung direkt gehen. Ihm sollte geraten werden, nach der Behandlung zwei Stunden lang nur weiche Nahrung und kalte Getränke zu sich zu nehmen und sich mindestens 4 bis 6 Stunden lang die Zähne nicht zu putzen.
8. Nach dem Trocknen kann der Lack unter Umständen „fleckig“ aussehen und sich von der Zahnoberfläche lösen.
Die Wirksamkeit des Produkts wird dadurch nicht beeinträchtigt, da sich nach wie vor eine komplette Lackschicht auf dem Zahn befindet.

Gegenanzeigen:

1. Ulzerative Gingivitis und Stomatitis
2. Bekannte allergische Reaktionen auf Fluorid
3. Verschlucken beim Auftragen vermeiden
4. Bekannte Allergien gegen Kolophonium oder ähnliche Materialien

Wechselwirkungen:

Nicht verwenden, wenn andere Fluoridbehandlungen (Gele oder Schäume) am selben Tag erfolgen sollen. Nach der ersten Behandlung sollte die Verwendung von Fluoridtabletten und -spülungen unterbrochen werden.

Nebenwirkungen:

In seltenen Fällen wurde von ödematösen Schwellungen berichtet, insbesondere nach dem Auftragen auf große Flächen. Atemnot ist bei Asthmatikern aufgetreten, wenn auch äußerst selten.
Patienten mit empfindlichem Magen berichteten gelegentlich von Übelkeit. Der Lack lässt sich einfach durch Bürsten und Spülen des Zahns entfernen.

SVENSKA ANVÄNDARINSTRUKTIONER

FluoroDose® 5 % natriumfluoridslack
Endast för lackanvändning

Bruksanvisning

FluoroDose är en välsmakande natriumfluoridslack som innehåller 50 mg natriumfluorid (motsvarar 22,6 mg fluoridjoner) per 1 ml. Den praktiska LoliTray™ enkeldosförpackningen gör att det går lätt att blanda och lägga på, så att resultatet blir jämnt.

Gör så här:

1. Rengör tänderna och ta bort så mycket fukt som möjligt från det område som ska behandlas.
2. Ta tag i folieöverdraget och dra av det långsamt, så att borsten och lackbrunnen kommer fram.
3. Ta bort borsten och blanda materialet i brunnen.
4. Lägg på ett tunt lager lack på det område som ska behandlas.
5. Låt lacken torka i cirka 10 sekunder och be sedan patienten att stänga munnen.
6. Kasta förpackningen och borsten efter användningen.
7. Patienten kan gå hem så snart behandlingen är klar. Rekommendera patienten att endast äta mjuk mat och dricka kalla drycker under två timmar efter behandlingen, och att inte borsta tänderna under minst 4-6 timmar.
8. Överskott av lack som har torkat kan se "fläckigt" ut och kan glida av tanden. Detta kommer inte att påverka produktens verkan eftersom det fortfarande ligger ett helt lager av lack på tanden.

Kontraindikationer:

1. Gingivit med sår och stomatit
2. Kända allergiska reaktioner mot fluor
3. Undvik att svälja under penslingen
4. Kända allergier mot kolofonium eller liknande material

Interaktioner:

Pensla inte om andra fluorbehandlingar (gel eller skum) ska göras samma dag.
Fluortabletter och fluorlösningar ska inte användas på flera dagar efter den inledande behandlingen.

Negativa reaktioner:

Ödematösa svullnader har rapporterats i sällsynta fall, i synnerhet efter pensling av stora ytor. Andnöd är visserligen väldigt sällsynt, men det har drabbat astmapatienter. Patienter med känsliga magar har ibland rapporterat om illamående. Lacken kan lätt tas av med tandborstning och sköljning.

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	[T] R25; [-] R32;
			Xi	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 at the site of contact. Wash immediately with plenty of soap and water.

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

Colour: Off-white

Odour: Characteristic odour

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.

 <i>Making Dentistry Easier.™</i>	 0482	CENTRIX INCORPORATED 770 River Road, Shelton, CT 06484 USA (203) 929-5582 (800) 235-5862 FAX (203) 929-6804 www.centrixdental.com
	 0482	EMERGO AUSTRALIA Level 20, Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000, Australia