

**TOPEX NEUTRAL FLUORIDE FOAM- sodium fluoride aerosol, foam  
Dentsply LLC. Professional Division Trading as "Sultan Healthcare"**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Topex Neutral Fluoride Foam**

**INDICATIONS AND USAGE**

Topex® Fluoride Foams are indicated for topical application to teeth to aid in the prevention of dental caries.

The non-acidic nature of Neutral pH (NaF) is recommended for patients with ceramic or composite restorations.

**DOSAGE AND ADMINISTRATION**

1. Remove cap from can. If this is the first time using can, break the protective shipping tab by gently lifting up the trigger.
2. Shake can thoroughly for at least 10 seconds before each use.
3. Completely invert can and slowly depress trigger to dispense foam into a fluoride tray
4. Air dry teeth thoroughly and insert tray into patient's mouth. Have patient close into the tray and use a slight chewing motion to ensure interproximal coverage.
5. Leave tray in contact with teeth between 1-4 minutes. Use a saliva ejector during treatment to minimize ingestion of product
6. Remove tray after elapsed time and have patient expectorate. Instruct patient to refrain from drinking, eating, or rinsing for 30 minutes after treatment.

Treatment frequency should not exceed 4 treatments per year.

**DOSAGE FORMS AND STRENGTHS**

APF topical Foam contains 2.73% sodium fluoride (1.23% fluoride ion).

NaF topical gel contains 2.0% sodium fluoride (0.9% fluoride ion).

**CONTRAINDICATIONS**

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

Do not swallow. Harmful if swallowed.

Keep out of reach of children.

This product is not intended for home or unsupervised consumer use.

Contents under pressure. Do not puncture or incinerate canister.

Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential.

Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

## **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, urticarial, gastric distress, headache, and weakness.

## **OVERDOSAGE**

If treatment dose is swallowed (less than 100 mg F ion), administer milk, limewater, or calcium-type antacid. In case of larger doses, use ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

## **DESCRIPTION**

Topex® Fluoride Foams are a family of topical fluoride foam products for professional application in trays. The family consists of APF Foam (1.23% fluoride ion at a pH between 3.0-4.5) and Neutral pH Foam (0.9% fluoride ion at a pH between 6.5 -7.5). Topex® Foam Fluoride products do not contain chlorofluorocarbon propellants.

## **STORAGE AND HANDLING**

Store at 20°C - 25°C (68° - 77°F); excursions permitted between 15°C - 30°C (59° - 86°F) [See USP Controlled room temperature.]

## **PRINCIPAL DISPLAY PANEL - Mixed Berry**

NDC 0699-0155-44  
REF AD31165

**Topex**  
**NEUTRAL**  
FLUORIDE FOAM  
*Mixed Berry*

Contains 2.0% Sodium Fluoride  
(0.9% Fluoride Ion)  


**Topex**  
**NEUTRAL**  
FLUORIDE FOAM  
*Mixed Berry*

**Topex**  
**NEUTRAL**  
FLUORIDE FOAM  
*Mixed Berry*

CONTAINS 1 CANISTER  
NET WEIGHT: 4.4 OZ. (125 g)

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**Topex**  
**NEUTRAL** FLUORIDE FOAM

Rx Only

**INDICATIONS AND USAGE**

For topical application to aid in the prevention of dental caries.  
**DOSSAGE AND ADMINISTRATION**  
Shake can thoroughly for at least 30 seconds before each use. Hold can completely upside down to dispense. Point can toward applicator tray and slowly press nozzle to fill tray. Dry tooth surface and insert tray(s) into mouth. Have patient bite down for 1 minute or up to 4 minutes. Remove tray(s) and have patient expectorate excess. Instruct patient not to eat, drink, or rinse for 30 minutes. Treatment frequency should not exceed 4 treatments per year.

**DOSSAGE FORMS AND STRENGTHS**

This topical foam contains 0.9% fluoride ion.

**CONTRAINDICATIONS**

Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- This product is not intended for home or unsupervised consumer use.
- Contents under pressure. Do not puncture or incinerate can.
- Safety and effectiveness below age 5 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential.

**OVERDOSSAGE**

If treatment dose is swallowed (or less than 100 mg fluoride ion), administer milk, lime-water, or calcium-lysine antacid. In case of larger doses (more than 100 mg fluoride ion), administer ippecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

**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.

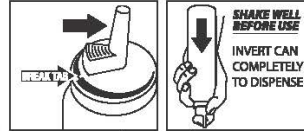
**INGREDIENTS**

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Polyethylene Glycol 400, Sodium Fluoride, Crodatas Q100-55, Cetyl Alcohol, Crodatas D3D-LQ, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Dibasic Anhydrous, Artificial Wildberry Flavor, Sodium Saccharin, Sodium Benzate

**STORAGE**

Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F) [see USP Controlled room temperature].

Made in USA Consult [www.sultanhealthcare.com](http://www.sultanhealthcare.com) for SDS and DFU.



Danger: Extremely flammable aerosol.  
Contains gas under pressure; may explode if heated.



0031165BX, R2-072017

Manufactured for:

 **Sultan**Healthcare

Sultan Healthcare  
1301 Smith Way • York, PA 17404 • USA  
Toll Free: 800-637-9582 • Phone: 201-871-1232  
Fax: 201-871-0321 • [www.sultanhealthcare.com](http://www.sultanhealthcare.com)

 **Sultan**Healthcare

## TOPEX NEUTRAL FLUORIDE FOAM

sodium fluoride aerosol, foam

### Product Information

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:0699-0155 |
| <b>Route of Administration</b> | DENTAL                  |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| <b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 0.02 g in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)              |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                |          |
| <b>BENZALDEHYDE</b> (UNII: TA269SD04T)                         |          |
| <b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)         |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                        |          |
| <b>APAFLURANE</b> (UNII: R40P36GDK6)                           |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                      |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)                     |          |
| <b>DIETHANOLAMINE OLETH-10 PHOSPHATE</b> (UNII: 55HSP2Q1LM)    |          |
| <b>DIETHANOLAMINE OLETH-3 PHOSPHATE</b> (UNII: Y67NX5905E)     |          |
| <b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F) |          |

## Product Characteristics

|                 |                     |                     |  |
|-----------------|---------------------|---------------------|--|
| <b>Color</b>    | WHITE               | <b>Score</b>        |  |
| <b>Shape</b>    |                     | <b>Size</b>         |  |
| <b>Flavor</b>   | BERRY (Mixed Berry) | <b>Imprint Code</b> |  |
| <b>Contains</b> |                     |                     |  |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0699-0155-44 | 1 in 1 CARTON  | 01/01/1997           |                    |
| 1 |                  | 125 g in 1 CANISTER; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG<br>OTHER |  | 01/01/1997           |                    |

**Labeler** - Dentsply LLC. Professional Division Trading as "Sultan Healthcare" (167087753)

## Establishment

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| Sciarra Laboratories, Inc. |         | 824900369 | MANUFACTURE(0699-0155) |