TOPEX 60 SECOND FLUORIDE FOAM BUBBLE FUN- sodium fluoride aerosol, foam
TOPEX 60 SECOND FLUORIDE FOAM GRAPE- sodium fluoride aerosol, foam
TOPEX 60 SECOND FLUORIDE FOAM SPEARMINT- sodium fluoride aerosol, foam
TOPEX 60 SECOND FLUORIDE FOAM ORANGE CREAM- sodium fluoride aerosol, foam
TOPEX 60 SECOND FLUORIDE FOAM STRAWBERRY- 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.

Topex 60 Second 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°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F) [See USP Controlled room temperature.]

MANUFACTURED FOR

Manufactured for:
Sultan Healthcare

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T oll Free: 800-637-8582 • Phone: 201-871-1232
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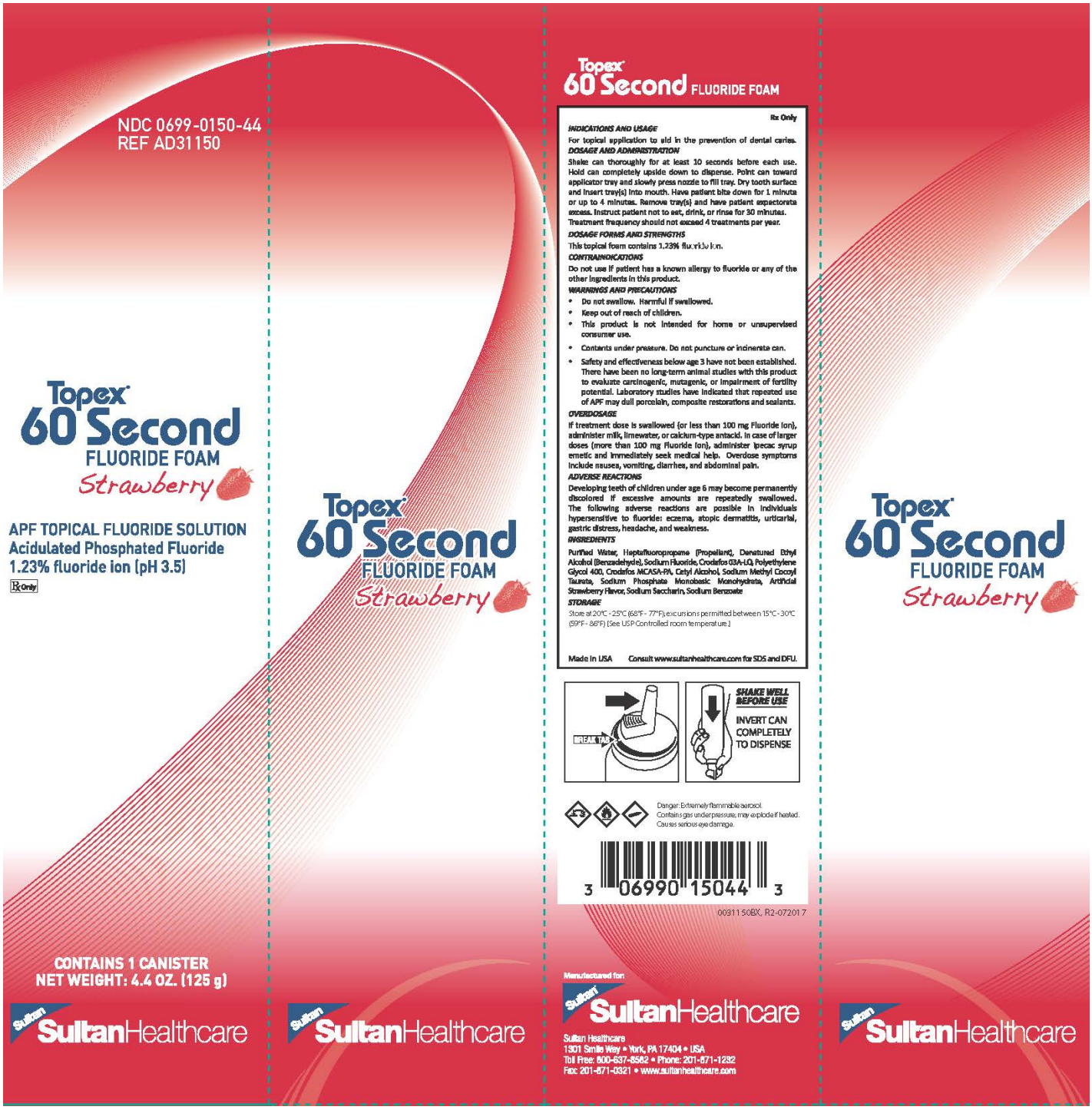
Made in USA

PRINCIPAL DISPLAY PANEL - Strawberry 4.4 oz



PRINCIPAL DISPLAY PANEL - Spearmint 4.4 oz

NDC 0699-0151-44
REF AD31151

Topex
60 Second
FLUORIDE FOAM
Spearmint

APF TOPICAL FLUORIDE SOLUTION
Acidulated Phosphated Fluoride
1.23% fluoride ion (pH 3.5)

℞ Only

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

SultanHealthcare

Topex
60 Second
FLUORIDE FOAM
Spearmint

SultanHealthcare

Topex
60 Second FLUORIDE FOAM

℞ Only

INDICATIONS AND USAGE

For topical application to aid in the prevention of dental caries.

DOSAGE AND ADMINISTRATION

Shake can thoroughly for at least 10 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.

DOSAGE FORMS AND STRENGTHS

This topical foam contains 1.23% 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 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.

OVERDOSAGE

If treatment dose is swallowed (or less than 100 mg Fluoride ion), administer milk, limewater, or calcium-type antacid. In case of larger doses (more than 100 mg Fluoride ion), administer ipecac 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, urticarial, gastric distress, headache, and weakness.

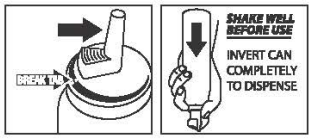
INGREDIENTS

Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Spearmint), Sodium Fluoride, Crodafos 03A-LQ, Polyethylene Glycol 400, Crodafos MCASA-PA, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Artificial Spearmint Flavor, Sodium Saccharin, Sodium Benzoate

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 for SDS and DFU.



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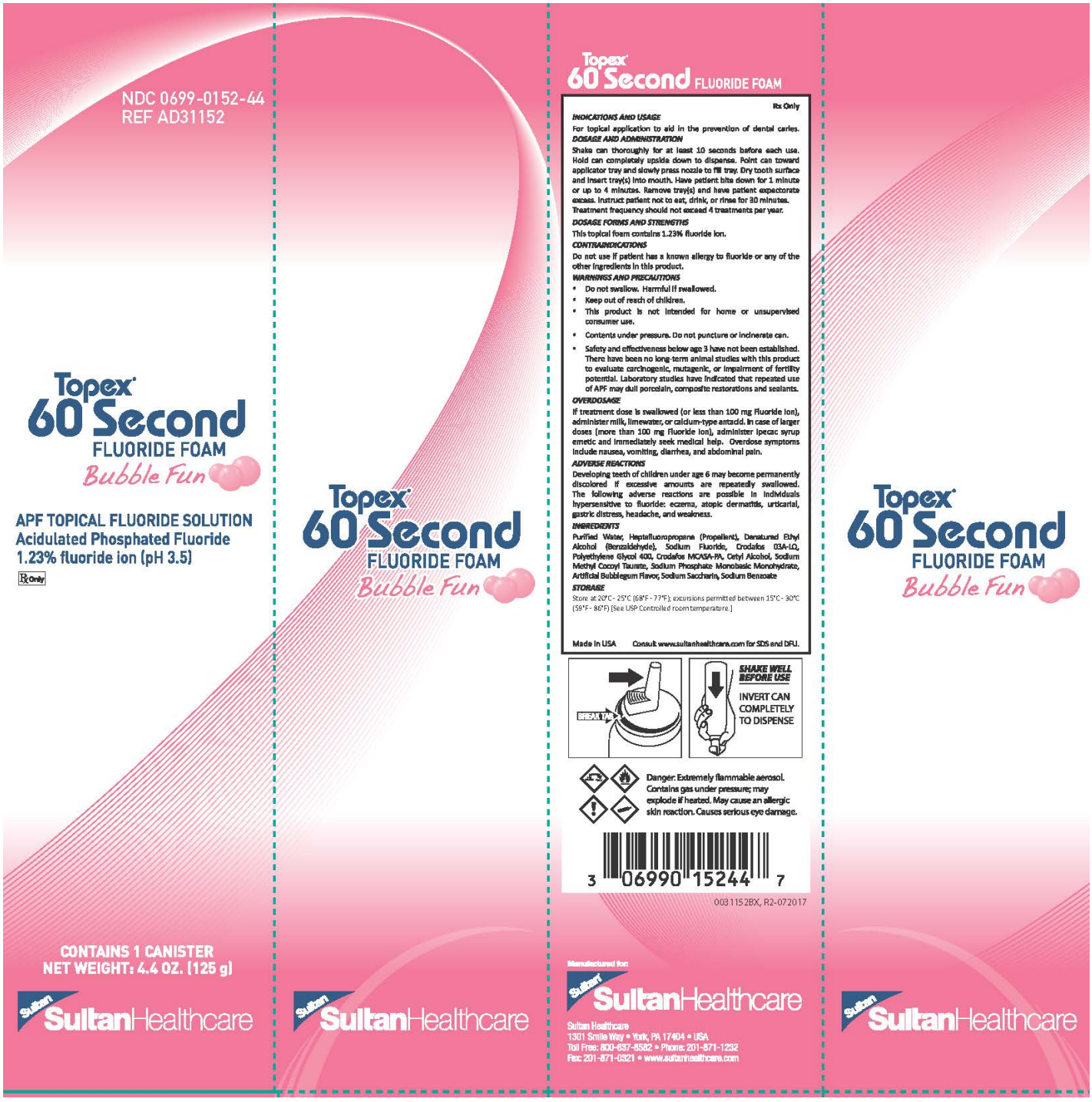
Topex
60 Second
FLUORIDE FOAM
Spearmint

SultanHealthcare

PRINCIPAL DISPLAY PANEL - Bubble Fun 4.4 oz



PRINCIPAL DISPLAY PANEL - Grape 4.4 oz

NDC 0699-0153-44
REF AD31153

Topex®
60 Second
FLUORIDE FOAM
Grape

APF TOPICAL FLUORIDE SOLUTION
Acidulated Phosphated Fluoride
1.23% fluoride ion (pH 3.5)

℞ Only

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

SultanHealthcare

Topex®
60 Second
FLUORIDE FOAM
Grape

SultanHealthcare

Topex®
60 Second FLUORIDE FOAM

Rx Only

INDICATIONS AND USAGE
For topical application to aid in the prevention of dental caries.

DOSAGE AND ADMINISTRATION
Shake can thoroughly for at least 10 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.

DOSAGE FORMS AND STRENGTHS
This topical foam contains 1.23% 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 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.

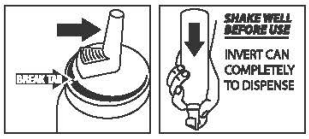
OVERDOSAGE
If treatment dose is swallowed (or less than 100 mg fluoride ion), administer milk, limewater, or calcium-type antacid. In case of larger doses (more than 100 mg fluoride ion), administer ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, 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, urticarial, gastric distress, headache, and weakness.

INGREDIENTS
Purified Water, Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Sodium Fluoride, Crodafos O3A-LQ, Polyethylene Glycol 400, Crodafos MCASA-PA, Cetyl Alcohol, Sodium Methyl Cocoyl Taurate, Sodium Phosphate Monobasic Monohydrate, Artificial Grape Flavor, Sodium Saccharin, Sodium Benzoate

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 for SDS and DFU.



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0031153BX, R2-07 2017

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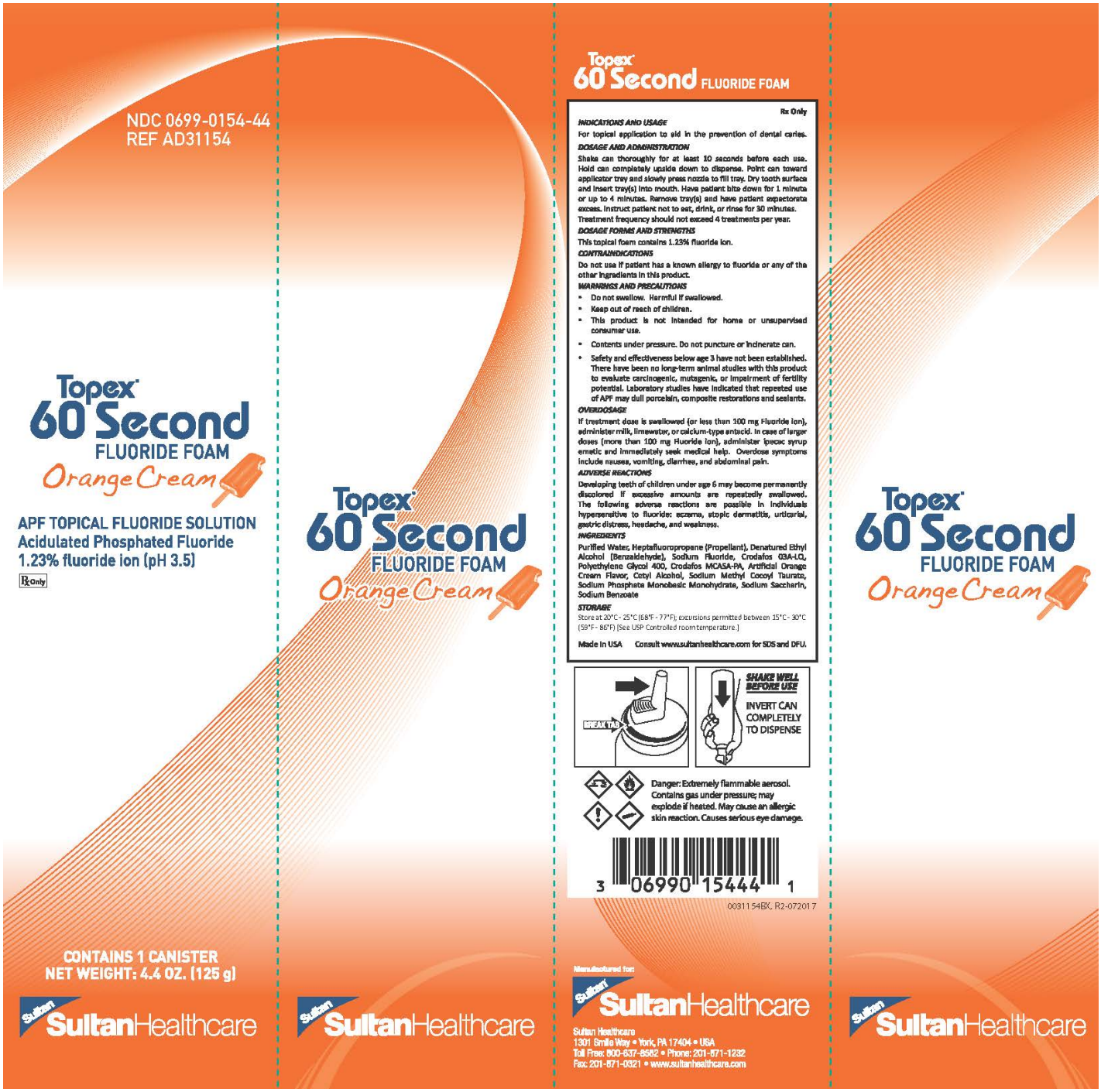
Topex®
60 Second
FLUORIDE FOAM
Grape

SultanHealthcare

PRINCIPAL DISPLAY PANEL - Orange Cream 4.4 oz



TOPEX 60 SECOND FLUORIDE FOAM BUBBLE FUN

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0152
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM (Bubble Fun)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0699-0152-44	1 in 1 BOX	01/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1997	

TOPEX 60 SECOND FLUORIDE FOAM GRAPE

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0153
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0699-0153-44	1 in 1 BOX	01/01/1997	02/12/2018
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1997	02/12/2018

TOPEX 60 SECOND FLUORIDE FOAM SPEARMINT

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0151
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
APAFLURANE (UNII: R40P36GDK6)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
BENZALDEHYDE (UNII: TA269SD04T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	MINT (Spearmint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0151-44	1 in 1 BOX	01/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1997	

TOPEX 60 SECOND FLUORIDE FOAM ORANGE CREAM

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0154
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL PHOSPHATE (UNII: VT07D6X67O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor	ORANGE (Orange Cream)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0699-0154-44	1 in 1 BOX	01/01/1997	01/31/2022
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

UNAPPROVED DRUG OTHER		01/01/1997	

TOPEX 60 SECOND FLUORIDE FOAM STRAWBERRY

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0150
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0150-44	1 in 1 BOX	01/01/1997	
1		125 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG 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(0699-0151, 0699-0150, 0699-0152, 0699-0153, 0699-0154)

Revised: 1/2024 Dentsply LLC. Professional Division Trading as "Sultan Healthcare"