TOPEX 60 SECOND FLUORIDE GEL- sodium fluoride gel
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 APF Fluoride Gel

Indications & Usage

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

Treatment frequency should not exceed 4 treatments per year.

Dosage & Administration

1. DO NOT USE IF SEAL IS BROKEN. Shake well before using.

2. Fill applicator tray no more than 1/3 full with Fluoride gel.

3. Dry tooth surface and insert tray in mouth.

4. Use suction throughout treatment.

5. Have patient bite down for a minimum of 60 seconds to a maximum of 4 minutes. (A slight biting or chewing motion will provide interproximal coverage)

6. Remove tray and have patient expectorate excess gel. Do not swallow.

7. Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

Dosage Forms & Strengths

This topical gel contains 1.23% sodium 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 & Precautions

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- May contain FD&C Yellow #5 or FD&C Yellow #6.
- This product is not intended for home or unsupervised consumer use.
- 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), administer milk, limewater, or calcium-type antacid. In case of larger doses (1 pint contains 4.5 grams F ion, which is a lethal dose), use ipecac syrup emetic and immediately seek medical help.

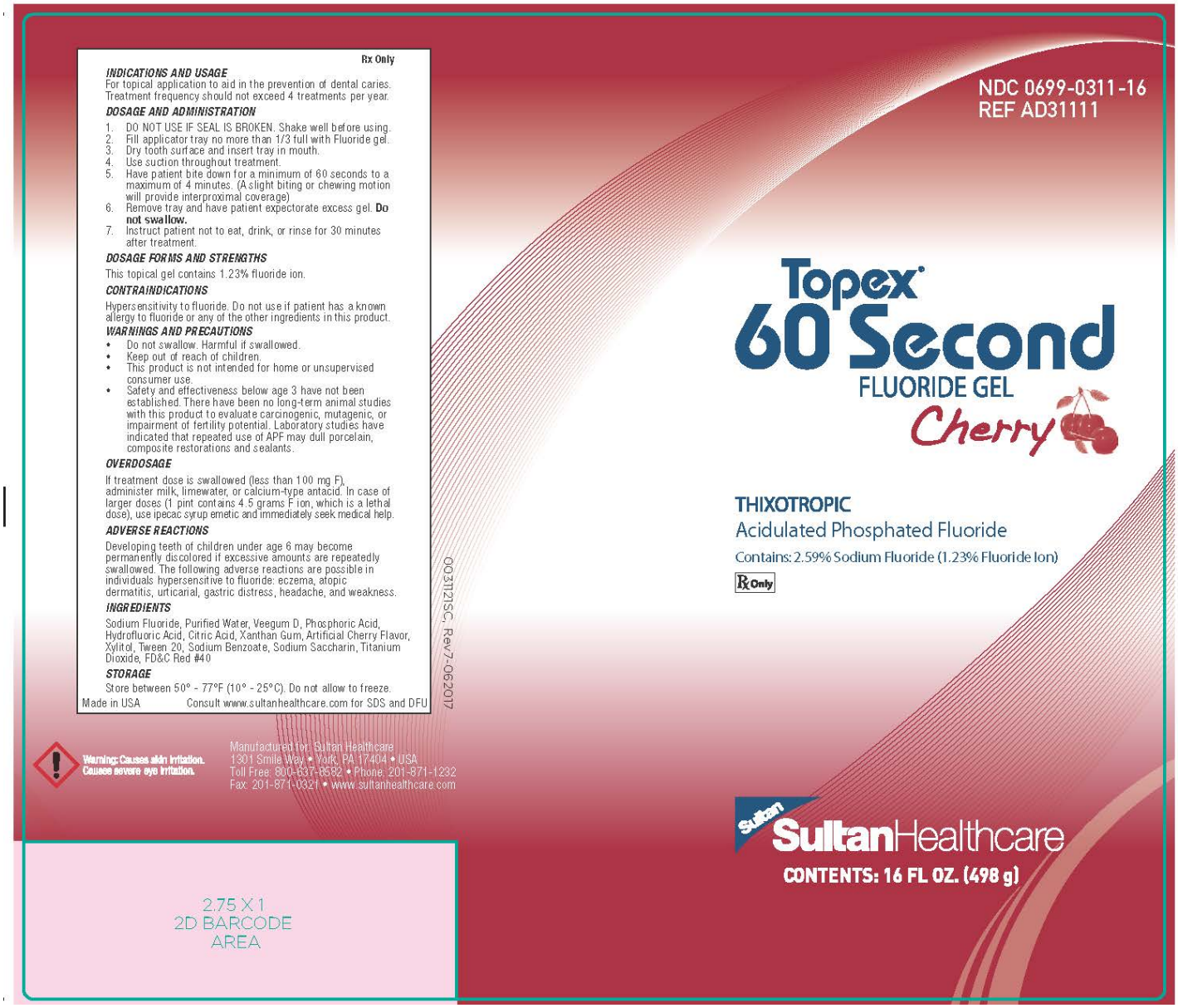
Description

Topex® Fluoride Gels are a family of topical fluoride gel products for professional application in trays.

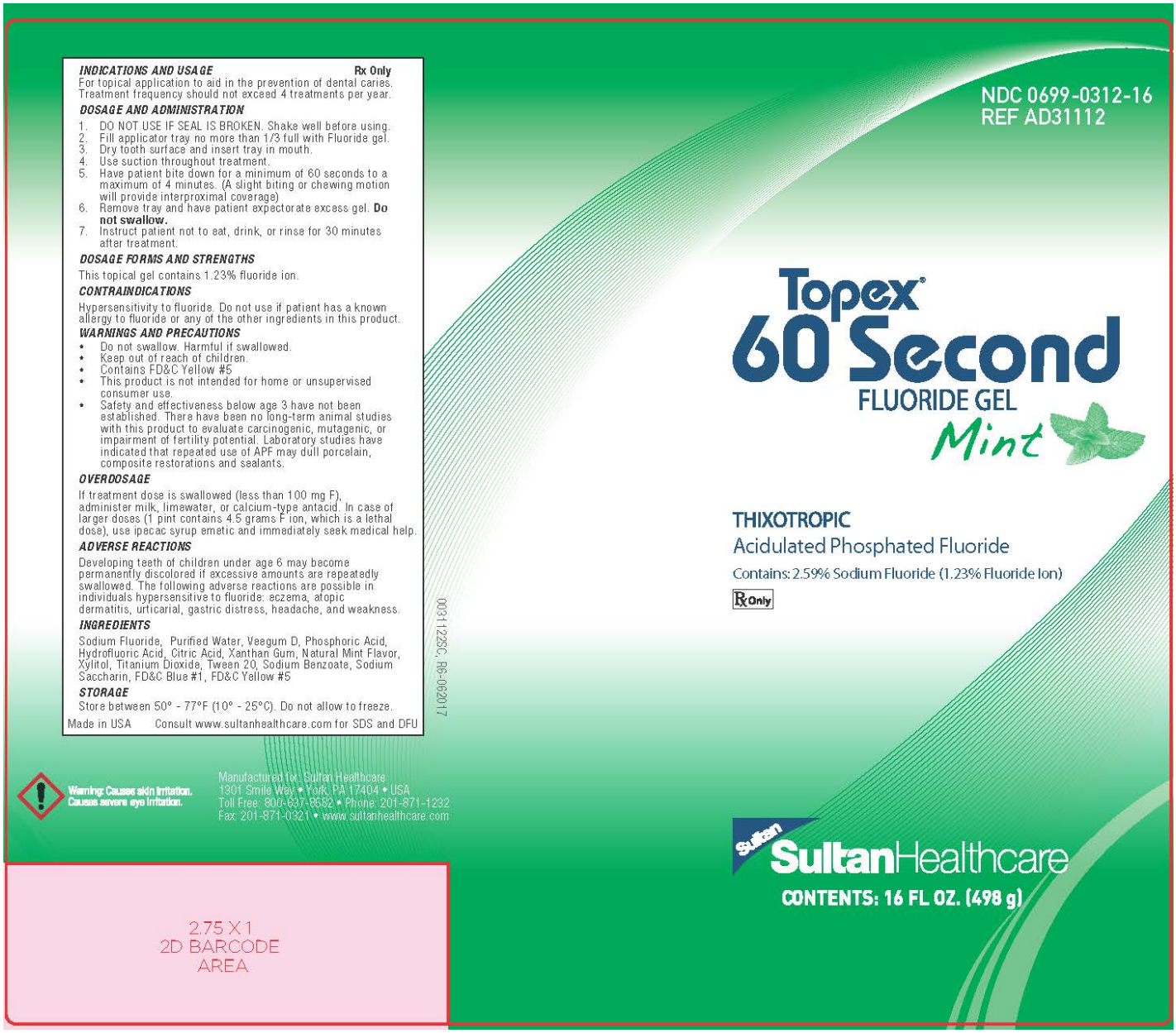
Storage

Store between 68° - 77°F (20° - 25°C). Do not allow to freeze.

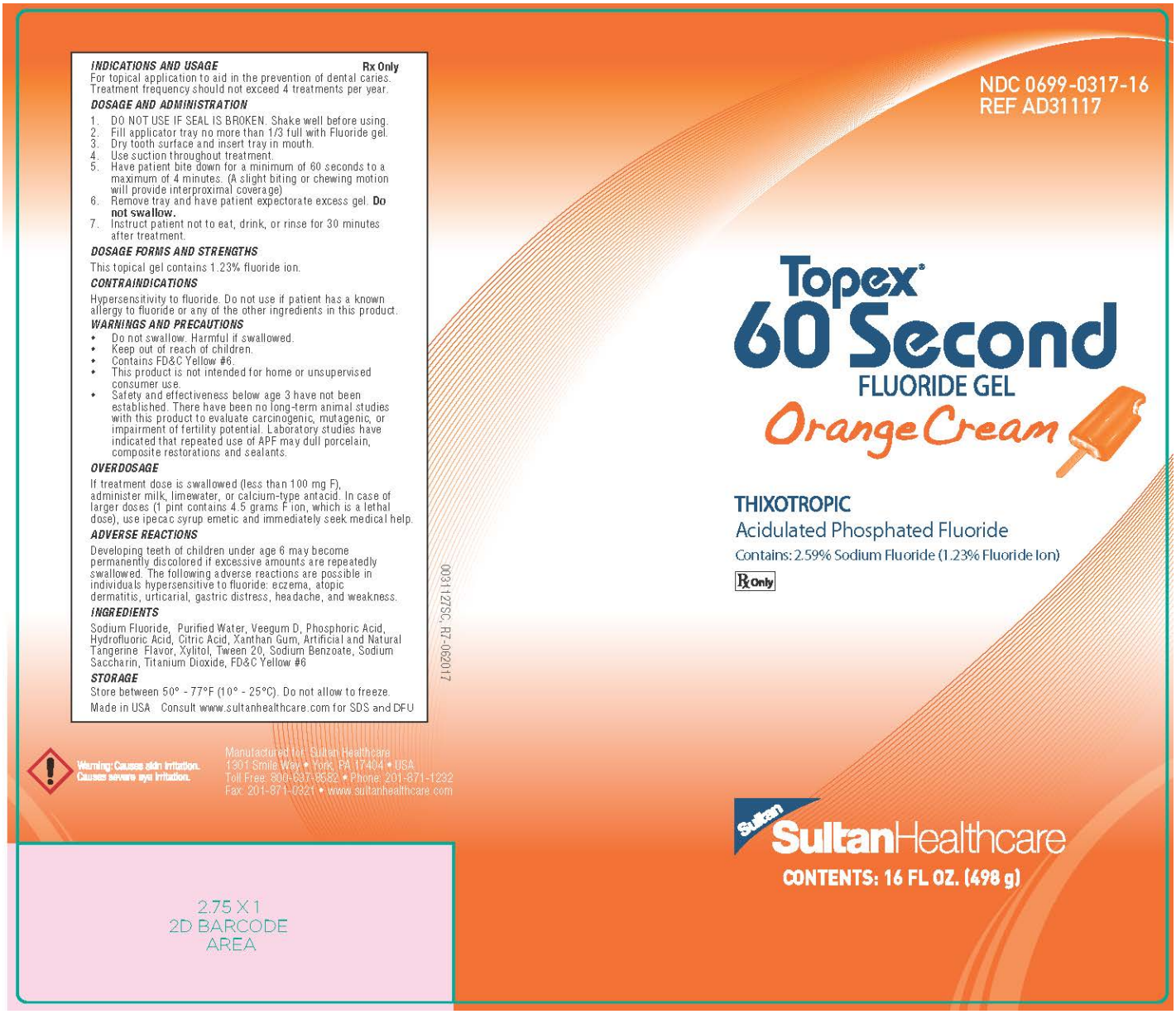
Principal display panel - Cherry



Principal Display Label - Mint



Principal Display Label - Orange Cream



TOPEX 60 SECOND FLUORIDE GEL

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0317
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TANGERINE (UNII: KH3E3096OO)	

Product Characteristics

Color	orange	**Score**	
Shape		**Size**	
Flavor	ORANGE (Orange Cream)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0317-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

TOPEX 60 SECOND FLUORIDE GEL

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0311
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0311-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

TOPEX 60 SECOND FLUORIDE GEL

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0312
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SPEARMINT (UNII: J7I2T6IV1N)	

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0312-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	manufacture(0699-0311, 0699-0312, 0699-0317)

Revised: 10/2017 Dentsply LLC. Professional Division Trading as "Sultan Healthcare"