

**HISMILE- sodium fluoride gel**  
**Accupac LLC**

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**Chupa Chup Cola Flavor Sodium Fluoride Anticavity Toothpaste**

**Active ingredient**

Sodium Fluoride 0.243%  
(0.14 w/v fluoride ion)

**Purpose**

Anticavity

**Use**

Aids in the prevention of dental cavities

**Warnings**

**When using this product**

Do not swallow  
Do not use in eye area

**Keep out of reach of children under 6 years of age**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Direction**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or doctor.  
Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).  
Supervise children as necessary until capable of using without supervision.  
Children under 2 years of age: Consult a dentist or doctor.

**Inactive ingredients**

Water, Sorbitol

Glycerin  
 Hydrated Silica  
 Xylitol  
 Sodium Phosphate  
 Xanthan Gum  
 Sodium Lauroyl Sarcosinate  
 Tetrapotassium Pyrophosphate  
 1,2-Hexadediol  
 Cellulose Gum  
 Sucralose  
 Lauryl Glucoside  
 Methyl Diisopropyl Propionamide  
 Sodium Gluconate  
 Zinc Lactate



## HISMILE

sodium fluoride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:44038-0322
<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)	SODIUM FLUORIDE	0.243 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COLA	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44038-0322-1	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/15/2024	

**Labeler** - Accupac LLC (071609663)

