

JASON POWERSMILE FLUORIDE PEPPERMINT ANTICAVITY- sodium fluoride gel

The Hain Celestial Group, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Jason Powersmile Anticavity Whitening Peppermint

Sodium Fluoride 0.24%

Anticavity

use: Prevention of cavities

Avoid storing at high temperatures (greater than 100°F). Protect from freezing. If you accidentally swallow more than used for brushing, seek professional assistance or contact Poison Control immediately.

Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact Poison Control Center immediately.

Prevent plaque and tartar buildup with regular brushing. **Adults and children 2 years of age or older** should brush teeth after each meal (or at least twice a day, or as directed by a dentist or doctor). **Children under 6:** To minimize swallowing, use a pea sized amount of paste and supervise brushing until good habits are established. **Children under 2, check with** a dentist or physician before using.

Glycerin, Water (Aqua), Hydrated Silica, Sodium Laurylglucosides Hydroxypropylsulfonate, Titanium Dioxide, Mentha Piperita (Peppermint) Oil, Chondrus Crispus (Carrageenan), Stevia Rebaudiana Leaf/Stem Extract, Citric Acid, Menthol, Sodium Bicarbonate, Sodium Chloride, Xanthan Gum, Sodium Benzoate

Active Ingredient/Active Moiety				
	Ingredient Name		Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.24 g in 100 g
Inactive Ingredients				
	Ingredient Name			Strength
	GLYCERIN (UNII: PDC6A3C0OX)			
	WATER (UNII: 059QF0KO0R)			
	HYDRATED SILICA (UNII: Y6O7T4G8P9)			
	SODIUM LAURYLGLUCOSIDES HYDROXYPROPYLSULFONATE (UNII: Z6GFR7R72Y)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
	PEPPERMINT OIL (UNII: AV092KU4JH)			
	CARRAGEENAN (UNII: 5C69YCD2YJ)			
	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
	STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)			
	MENTHOL, (+)- (UNII: C6B1OE8P3W)			
	SODIUM CHLORIDE (UNII: 451W47IQ8X)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
	SODIUM BENZOATE (UNII: OJ245FE5EU)			
	SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-0600-1	1 in 1 CARTON	02/01/2021	
1		119 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	02/01/2021		

Labeler - The Hain Celestial Group, Inc. (117115556)

Registrant - The Hain Celestial Group, Inc. (014334364)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		081512382	manufacture(61995-0600)