

**JASON HEALTHY MOUTH ANTICAVITY TARTAR CONTROL TEA TREE  
CINNAMON- sodium monofluorophosphate 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.*

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**Healthy Mouth Toothgel**

Anticavity

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 physician). **Children under 6:** Should use only a pea sized amount of paste and be supervised as necessary. **Children under 2, check with a dentist or physician before using.**

Glycerin, Aqua (Water), Hydrated Silica, Sodium Cocoyl Glutamate, Xylitol, Cinnamomum Zeylanicum (Cinnamon) Leaf Oil, Eugenia Caryophyllus (Clove) Flower Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil (1), Melia Azadirachta Seed Oil, Aloe Barbadensis Leaf Juice (1), Bambusa Arundinacea Stem Powder, Carum Petroselinum (Parsley) Extract, Citrus Grandis (Grapefruit) Seed Extract, Perilla Ocymoides Seed Extract, Stevia Rebaudiana Leaf/Stem Extract, Ascorbic Acid, Tocopheryl Acetate, Calcium Carbonate, Cellulose Gum, Citric Acid, Menthol, Sea Salt, Sodium Bicarbonate, Sodium Magnesium Silicate, Ubiquinone, Eugenol

(1) Certified Organic Ingredients

(2) Coenzyme Q10

Use: Prevention of cavities

Sodium Monofluorophosphate 0.76%





# JASON HEALTHY MOUTH ANTICAVITY TARTAR CONTROL TEA TREE CINNAMON

sodium monofluorophosphate gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61995-0525
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.76 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>CLOVE OIL</b> (UNII: 578389D6D0)	

<b>AZADIRACHTA INDICA SEED OIL</b> (UNII: 4DKJ9B3K2T)
<b>CINNAMON BARK OIL</b> (UNII: XE54U569EC)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM COCOYL GLUTAMATE</b> (UNII: BMT4RCZ3HG)
<b>XYLITOL</b> (UNII: VCQ006KQ1E)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>BAMBUSA ARUNDINACEA STEM</b> (UNII: NRA4497HC5)
<b>GRAPEFRUIT SEED OIL</b> (UNII: 598D944HOL)
<b>PARSLEY</b> (UNII: 58FMD0Q0EV)
<b>PERILLA FRUTESCENS SEED</b> (UNII: 8M62PUD356)
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)
<b>UBIDECARENONE</b> (UNII: EJ27X76M46)
<b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)
<b>SEA SALT</b> (UNII: 87GE52P74G)
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)
<b>EUGENOL</b> (UNII: 3T8H1794QW)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-0525-6	1 in 1 CARTON	09/20/2017	
1		170 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	09/20/2017	

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

**Registrant** - The Hain Celestial Group, Inc. (081512382)

### Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		081512382	manufacture(61995-0525)

