

JASON SEA FRESH ANTICAVITY DEEP SEA SPEARMINT- 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.

Jason Sea Fresh Anticavity Deep Sea Spearmint

Sodium Monofluorophosphate 0.76%

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 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), Silica, Sodium Cocoyl Glutamate, Xylitol, Mentha Viridis (Spearmint) Leaf Oil, Aloe Barbadensis Leaf Juice (1), Aphanizomenon Flos-Aquae Powder, Bambusa Arundinacea Stem Powder, Carum Petroselinum (Parsley) Extract, Citrus Grandis (Grapefruit) Seed Extract, Perilla Ocymoides Seed Extract, Stevia Rebaudiana Leaf/Steam Extract, Calcium Carbonate, Cellulose Gum, Dimethyl Sulfone, Sea Salt, Tocopheryl Acetate, Sodium Bicarbonate, Sodium Magnesium Silicate, Sodium Sulfate, Ubiquinone (2).

(1) Certified Organic Ingredients

(2) Coenzyme Q10



JASON SEA FRESH ANTICAVITY DEEP SEA SPEARMINT

sodium monofluorophosphate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-0530
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CHLORELLA PYRENOIDOSA (UNII: 591BV50NV8)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
XYLITOL (UNII: VCQ006KQ1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BAMBUSA ARUNDINACEA STEM (UNII: NRA4497HC5)	
CITRUS MAXIMA SEED (UNII: 083X55C543)	
PARSLEY (UNII: 58FMD0Q0EV)	
PERILLA FRUTESCENS SEED (UNII: 8M62PUD356)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SPEARMINT OIL (UNII: C3M81465G5)	
UBIDECARENONE (UNII: EJ27X76M46)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
SEA SALT (UNII: 87GE52P74G)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-0530-6	1 in 1 CARTON	09/29/2017	
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	09/29/2017	

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(61995-0530)

