

SPEARMINT WHITENING WITH HEMP OIL- sodium monofluorophosphate paste, dentifrice **Whole Foods**

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.

Active ingredient Purpose

Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion) Anticavity

Use aids in the prevention of dental cavities

Warnings

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.

Directions

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice per day, or 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 glycerin, water, calcium carbonate, hydrated silica, xylitol, sodium bicarbonate, carrageenan, cannabis sativa (hemp) seed oil, sodium auroyl sarcosinate, natural flavor, zinc citrate, benzyl alcohol



Spearmint with Fluoride

Toothpaste

with Hemp Seed Oil

Cavity Fighting & Whitening Net wt 5.5 oz (156g)

SPEARMINT WHITENING WITH HEMP OIL

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42681-0019
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ZINC CITRATE (UNII: K72I3DEX9B)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
XYLITOL (UNII: VCQ006KQ1E)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42681-0019-1	156 g in 1 TUBE; Type 0: Not a Combination Product	04/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/29/2020	

Labeler - Whole Foods (196175616)**Registrant** - Lornamead (080046441)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(4268 1-00 19)

Revised: 4/2020

Whole Foods