

**SPEARMINT AND PEPPERMINT PLAQUE A WAY FLUORIDE ANTICAVITYGENTLE FORMULA GENTLE FORMULA- sodium fluoride paste, dentifrice  
SLH Optimal Health LLC**

*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.*

**Spearmint and Peppermint PLAQUE A WAY Fluoride Anticavity Toothpaste Gentle Formula**

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**Active Ingredient**

Sodium fluoride 0.24% (0.14 w/v fluoride ion)

**Purpose**

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 and over	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
children under 6 years of age	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 a supervision.
children under 2 years of age	Consult a dentist or doctor.

**Inactive Ingredients**

WATER, DICALCIUM PHOSPHATE, SORBITOL, GLYCERIN, SODIUM LAURYL SULFATE, ANNATTO ( BIXA ORELLANA) SEED EXTRACT, SODIUM HYDROXIDE, NATURAL AND ARTIFICIAL FLAVORS, DISODIUM EDTA, CELLULOSE GUM, SODIUM SACCHARIN, TETRASODIUM PYROPHOSPHATE, FD AND C BLUE NO.1

**Spearmint and Peppermint PLAQUE A WAY Fluoride Anticavity Toothpaste Gentle Formula  
116g (42288-000-04)**

**Spearmint and Peppermint**

**PLAQUE A WAY**



**Fluoride Anticavity Toothpaste  
Gentle Formula**

**Net Wt. 4.1 oz (116 g)**

**Drug Facts**

**Active ingredient** **Purpose**  
Sodium fluoride 0.24% (0.14% w/v fluoride ion).....Anticavity

**Use** Aids in the prevention of dental cavities.

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children under 2 years of age	Consult a dentist or doctor.

**Drug Facts (continued)**

**Inactive ingredients** WATER, DICALCIUM PHOSPHATE, SORBITOL, GLYCERIN, SODIUM LAURYL SULFATE, ANNATTO (BIXA ORELLANA) SEED EXTRACT, SODIUM HYDROXIDE, NATURAL AND ARTIFICIAL FLAVORS, DISODIUM EDTA, CELLULOSE GUM, SODIUM BENZOATE, SODIUM SACCHARIN, TETRASODIUM PYROPHOSPHATE, FD&C BLUE NO. 1

SLH OPTIMAL HEALTH LLC  
10075 JOG RD, SUITE 301  
BOYNTON BEACH, FL 33437  
UNITED STATES

LOT ?

**SPEARMINT AND PEPPERMINT PLAQUE A WAY FLUORIDE  
ANTICAVITYGENTLE FORMULA GENTLE FORMULA**

sodium fluoride paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42288-000
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.24 g in 100 g

  

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BIXA ORELLANA SEED (UNII: O87354RZ5A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

  

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	SPEARMINT (SPEARMINT) , PEPPERMINT (PEPPERMINT)	Imprint Code	
Contains			

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42288-000-04	116 g in 1 TUBE		

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/03/2012	

**Labeler** - SLH Optimal Health LLC (031081015)

**Registrant** - SLH Optimal Health LLC (031081015)

### Establishment

Name	Address	ID/FEI	Business Operations
SLH Optimal Health LLC		031081015	manufacture(42288-000)