

**MASTIC DENT WHITENING- sodium fluoride paste, dentifrice**  
**Chia Gi LTD**

*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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**Active Ingredients**

Drug Facts:

Active Ingredients:

- Sodium Fluoride 0.22% (0.12% w/v fluoride ion) - Anticavity

**Warnings**

**Warnings:**

- **When using this product**, if irritation occurs discontinue use.
- **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 a poison control Center right away.

**Dosage**

Use a pea-sized amount

**Keep out of reach.**

**Keep out of reach of children under 6 years of age.**

**Directions**

Directions:

- **Adults and children 2 years and older.**
- Brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
- Instruct in good brushing and rinsing habits (to minimize swallowing).
- **Children under 2 years** do not use unless directed by a dentist or a physician.

**Inactive Ingredients**

Inactive Ingredients:

Water, Sorbitol, Hydrated Silica, Glycerine, Sodium Lauroyl Sarcosinate, Peg-8, Calcium Pyrophosphate, Fragrance, Xanthan Gum, Titanium Dioxide, Chamomilla Recutita, Camelia Sinensis, Menthol Crystals, Sodium Saccharin, Allantoin, Pistacia Lentiscus (Mastic) Gum, Bisabolol, Glycyrrhetic Acid, Sodium Hydroxide

**Information of owner**

Product Of Chios

CHIA GI LTD

144 AG. MINA, HIOS, 82100  
GREECE

Tel.: 30-22710-33101, FAX: 30-22710-32229  
 www.masticspa.com  
 Made In Greece

## PURPOSE SECTION

Aids in the prevention of dental cavities-plaque

## Image of Label



MASTIC DENT WHITENING			
sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15304-4182
Route of Administration	ORAL, DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.2 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ENOXOLONE (UNII: P540XA09DR)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALLANTOIN (UNII: 344S277G0Z)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
MENTHOL (UNII: L7T10EIP3A)	
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
.ALPHA.-BISABOLOL, (-) (UNII: 36HQN158VC)	
CHAMOMILE (UNII: FGL3685T2X)	
CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT (Mint Flavor)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15304-4182-1	75 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/22/2005	

**Labeler** - Chia Gi LTD (363215270)

**Registrant** - Chia Gi LTD (363215270)

### Establishment

Name	Address	ID/FEI	Business Operations
Chia Gi LTD		363215270	label(15304-4182) , manufacture(15304-4182) , pack(15304-4182)