

SUPERSMILE- sodium monofluorophosphate paste, dentifrice
Robell Research, 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.

Drug Facts

Active Ingredient:

Sodium Monofluorophosphate
(0.14% w/v Fluoride Ion)

Purpose:

Anticavity toothpaste

Uses:

Aids in the prevention of dental cavities.

Warnings:

As with all fluoride toothpastes, keep out of reach of children under 6 years old.

If you accidentally swallow more than used for brushing, get medical help or call a Poison Control Center right away.

Directions:

For best results: Brush teeth thoroughly after each meal, at least twice a day, or as directed by a dentist. Instruct children under six about good brushing and rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Under two years of age consult a dentist or a doctor before use.

Inactive Ingredients

Water, Sorbitol, Dicalcium Phosphate Dihydrate, Sodium Bicarbonate, Calcium Carbonate, Titanium Dioxide, Cellulose Gum, Calprox®, Sodium Perborate, Flavor, Corn Starch, Magnesium Carbonate, Sodium Lauryl Sulfoacetate, Sodium Saccharin

Created by,

□**DR. IRWIN SMIGEL**

□World Renowned

Father of Aesthetic

Dentistry

For best results, place a pearlsize drop of Whitening Toothpaste on a **DRY** toothbrush and brush in a circular motion for two minutes twice daily.

Three month supply (when used as directed)

☐ **Whitens** ☐- Calprox® safely lifts surface stains, maintains and enhances the vibrancy of professionally bleached teeth, and restores bonding, caps, veneers and dentures to their original whiteness.

☐ **Freshens** ☐- Lasting germicidal protection.

☐ **Strengthens** - ☐Remineralizes tooth enamel.

☐ **Protects** ☐- Fluoride prevents cavities.

☐ **Safely** ☐- No harsh abrasives, no sensitivity.

STORE IN A COOL PLACE. RECYCLABLE

DETERMINE YOUR SMILE CARE NEEDS WITH A PERSONALIZED PROFILE AT
WWW.SUPERSMILE.COM

QUESTIONS: 1-800-784-SMILE or INFO@SUPERSMILE.COM

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Principal Display Panel

supersmile®

ORIGINAL MINT

professional

whitening

toothpaste

Contains fluoride.

4.2 oz / 119 g



SUPER

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SUPERSMILE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53567-0552
Route of Administration	ORAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: 07TSZ97GEP)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CALCIUM PEROXIDE (UNII: 7FRO2ENO91)	
SODIUM PERBORATE (UNII: Y52BK1W96C)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (ORIGINAL MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53567-0552-6	227 g in 1 TUBE		
2	NDC:53567-0552-3	6 g in 1 TUBE		
3	NDC:53567-0552-5	14 g in 1 TUBE		
4	NDC:53567-0552-8	40 g in 1 TUBE		
5	NDC:53567-0552-2	1 in 1 BOX		
5		119 g in 1 TUBE		
6	NDC:53567-0552-1	1 in 1 BOX		
6		50 g in 1 TUBE		

Supersmile®

ORIGINAL MINT

professional
whitening
toothpaste

Contains fluoride.
4.2 oz / 119 g



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/2014	

Labeler - Robell Research, Inc. (155571656)

Revised: 3/2015

Robell Research, Inc.