SUPERSMILE PROFESSIONAL WHITENING- 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, children under 6 years old.

Directions:

For best results: Brush teeth thoroughly after each meal, at least twice a day, or as directed by a dentist.

Directions:

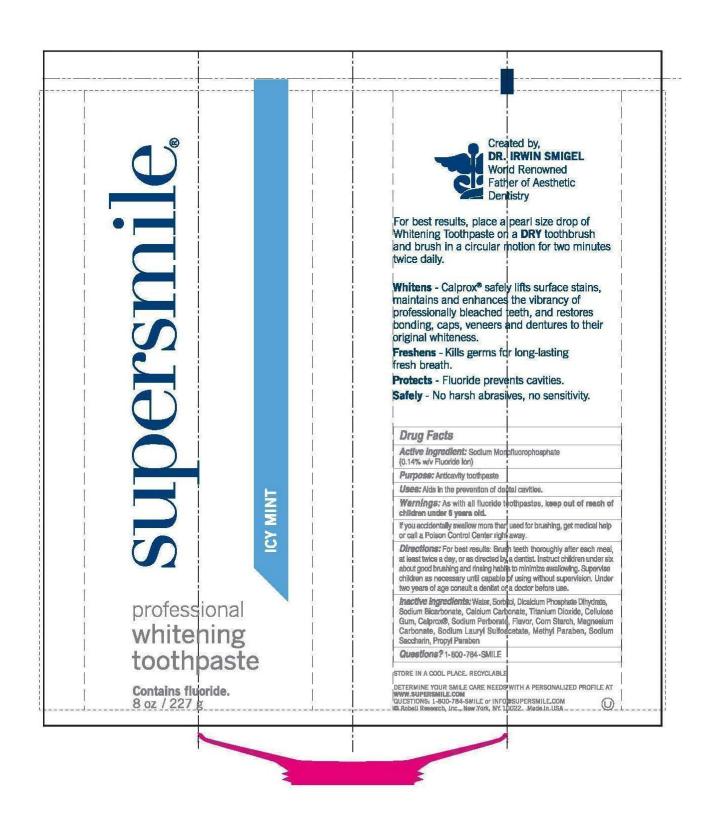
Instruct children under six about good brushing and rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Under two years of age consult a dentist or a doctor before use.

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, Methyl Paraben, Sodium Saccharin, Propyl Paraben

Questions:

1-800 -784 -SMILE



SUPERSMILE PROFESSIONAL WHITENING

toothpaste paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:53567-6044
Route of Administration	DENTAL	DEA Schedule	

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	SODIUM MONOFLUOROPHOSPHATE (MONOFLUOROPHOSPHATE ION)	MONOFLUOROPHOSPHATE ION	0.83 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER	
CALCIUM PERO XIDE	
SO DIUM PERBORATE	
SO DIUM BICARBO NATE	
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US	
CALCIUM CARBONATE	
MAGNESIUM CARBONATE	
STARCH, CORN	
SACCHARIN	
METHYLPARABEN	
PROPYLPARABEN	
TITANIUM DIO XIDE	
CARBO XYMETHYLCELLULO SE SO DIUM	
SODIUM LAURYL SULFOACETATE	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53567-6044-2	227 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/28/2011	

Labeler - Robell Research, Inc. (155571656)

Registrant - Loranmead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(53567-6044), pack(53567-6044)

Revised: 10/2012 Robell Research, Inc.