SUPERSMILE PROFESSIONAL WHITENING- fluoride 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.

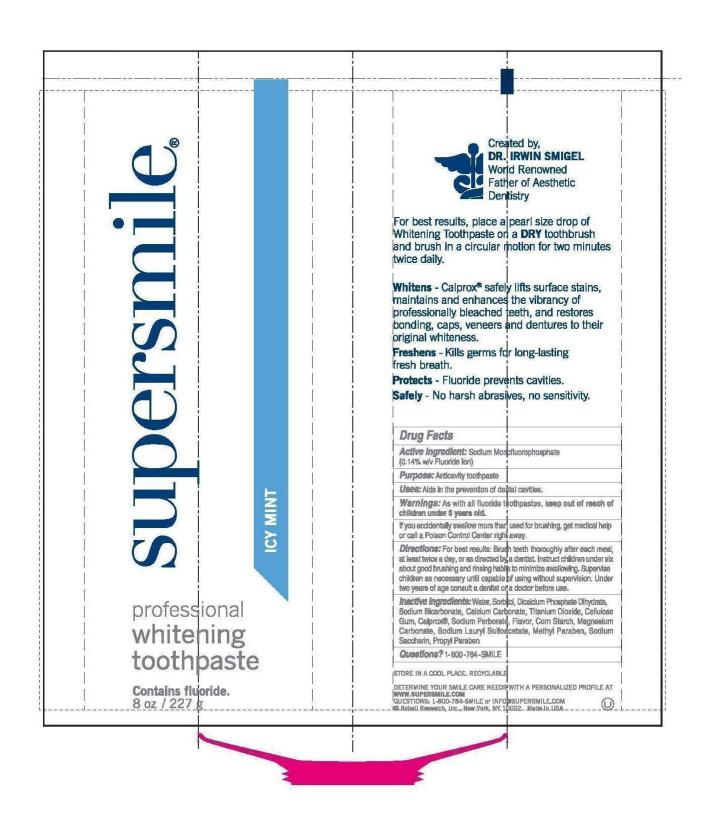
Inactive Ingredients:

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

Tube Label



SUPERSMILE PROFESSIONAL WHITENING

fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53567-0101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.76 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CALCIUM PERO XIDE (UNII: 7FRO2ENO91)		
SODIUM PERBORATE (UNII: Y52BK1W96C)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)		
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)		
MAGNESIUM CARBO NATE (UNII: 0 E53J9 27NA)		
STARCH, CORN (UNII: O8232NY3SJ)		
SACCHARIN (UNII: FST467XS7D)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 O B S 3 1 1)		
SODIUM LAURYL SULFOACETATE (UNII: D0 Y70 F2B9J)		

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53567-0101-6	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 - Lornamead (126440440)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lornamead		126440440	manufacture(53567-0101), pack(53567-0101)	

Revised: 10/2012 ROBELL RESEARCH, INC.