

**SUPERSMILE PROFESSIONAL WHITENING- toothpaste 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.*

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**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

Contains fluoride.  
8 oz / 227 g

ICY MINT



Created by,  
**DR. IRWIN SMIGEL**  
World Renowned  
Father of Aesthetic  
Dentistry

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

**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** - Kills germs for long-lasting fresh breath.

**Protects** - Fluoride prevents cavities.

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

#### 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 Sulfosuccinate, Methyl Paraben, Sodium Saccharin, Propyl Paraben

**Questions?** 1-800-784-SMILE

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**SUPERSMILE PROFESSIONAL WHITENING**

toothpaste paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53567-6044
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (MONOFLUOROPHOSPHATE ION - UNII:4964UZ79MI)	MONOFLUOROPHOSPHATE ION	0.83 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
CALCIUM PEROXIDE (UNII: 7FRO2ENO91)	
SODIUM PERBORATE (UNII: Y52BK1W96C)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN (UNII: FST467XS7D)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

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

**Marketing Information**

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

**Registrant** - Loranmead (126440440)

**Establishment**

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

Revised: 10/2012

Robell Research, Inc.