

THERABREATH TOOTHPASTE - sodium fluoride gel, dentifrice
220 LABORATORIES 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.

ThereBreath Packaging

Directions: Cover the bristles of a dry tooth brush with TheraBreath Toothpaste and brush teeth, tongue, and palate for 2 minutes.

Keep out of reach of children.

If spilled on fabrics, wash out immediately. This product was sealed with protective packaging at the laboratory. If seal is missing, do not use.

Naturally Oxygenating

Professional Formula
TheraBreath
Dentist Recommended
Fresh Breath
Toothpaste

No Sodium Lauryl Sulfate
With Aloe Vera for Health Gums
Works Instantly - Reverses Dry Mouth
24 HR Confidence Guaranteed

End Edge of Untrimmed, Unsealed Tube

Seal Trim



128 mm

Shoulder

Flip-closure Cap Bottom Edge

RIK VIG DESIGN		Date: 8/13/09	Version Number: 2.0								
20525 Germain Street, Chatsworth, California 91311 • 818.718.2754 • Cell 818.521.1567 • rik@rikvigndesign.com											
<p>Client: DR. HAROLD KATZ, INC. Project: TheraBreath Toothpaste Tube Direct REVISED Version 2</p> <p>Notes: The Pantone 376c Green should be custom mixed to match the exact target green chosen by the client for their new molded Oral Rinse Bottle. Check with Ray facteau for a sample.</p>	<p>Colors:</p> <table border="0"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pantone 1505c</td> <td>Pantone 342c</td> <td>Pantone 361c</td> <td>Pantone Black</td> </tr> </table>					Pantone 1505c	Pantone 342c	Pantone 361c	Pantone Black	<p>Software: MAC - Adobe Illustrator CS3</p>	
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THERABREATH TOOTHPASTE

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57367-033
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	24 mg in 10 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORITE (UNII: G538EBV4VF)	
ALOE (UNII: V5VD430YW9)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT (PEPPERMINT OIL)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57367-033-18	113.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/03/2010	

Labeler - 220 LABORATORIES INC (783247950)

Registrant - 220 LABORATORIES INC (783247950)

Establishment

Name	Address	ID/FEI	Business Operations
220 LABORATORIES INC		783247950	manufacture

Revised: 3/2010

220 LABORATORIES INC