KOALA PALS BERRYLICIOUS- sodium fluoride paste, dentifrice
Melaleuca, 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.

KP Fluoride Tooth Gel Content of Label

Active ingredient
Sodium Fluoride 0.24% (fluoride ion 0.15% w/v)

Purpose
Anticavity

Use aids in the prevention of cavities

Warnings
Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 2 years of age and older:** brush teeth thoroughly, preferably after each meal, or at least twice a day or as directed by a dentist or doctor
- **children 2 to 6 years:** use only a pea-sized amount and supervise child's brushing and rinsing (to minimize swallowing)
- **children under 2 years of age:** ask a dentist or doctor

Inactive ingredients acesulfame potassium, citric acid, flavor, glycerin, hydrated silica, natural lemon and orange flavor extracts, potassium sorbate, sodium benzoate, sodium bicarbonate, sodium lauroyl sarcosinate, sorbitol, water, xanthan gum, xylitol

koala pals®

berrylicious flavor fluoride tooth gel

NET WT. 3.8 OZ (108 g)

Melaleuca

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koala pals®

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* naturally derived / dérivé naturel
† vegetable-derived / dérivé végétal
‡ food grade / de grade alimentaire
§ baking soda / bicarbonate de soude

Melaleuca, Inc., Idaho Falls, ID
83402-6003, To order: 1-800-282-3000
www.melaleuca.com
Product of USA N° 1297 04/10U

NOT FOR RESALE IN CANADA

100% SATISFACTION GUARANTEE

Warnings

KOALA PALS BERRYLICIOUS

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54473-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.2592 g in 108 g

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54473-204-04	108 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/01/2010	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc._Knoxville		805617610	manufacture