

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

Warnings


koala pals®
berrylicious
flavor
fluoride
tooth
gel



NET WT. 3.8 OZ (108 g)

 Melaleuca

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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



sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	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 SARCO SINATE (UNII: 632GS99618)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-300-04	108 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

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(54473-300)