

ZINC OXIDE LIP BALM PINA COLADA- zinc oxide lip balm pina colada stick
Private Label Select Ltd CO

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.

Beauty By Earth SPF 15 Lip Balm Pina Colada

OTC ACTIVE INGREDIENT

Drug Facts	
Active Ingredients	Purpose
Non-Nano Uncoated Zinc Oxide 10.5%.....	Sunscreen

OTC PURPOSE SECTION

Drug Facts

Active Ingredients

Non-Nano Uncoated Zinc Oxide 10.5%.....

Purpose

Sunscreen

OTC KEEP OUT OF REACH OF CHILDREN

Drug Facts *(continued)*

Uses ■ Helps prevent sunburn

Warnings

For external use only • Do not use on open wounds. • Stop use and ask physician if rash occurs. • **Keep out of reach of children.**

ARTWORK - OUTSIDE

Sealed for your protection. TWIST TO BREAK SEAL.

Drug Facts (continued)

Uses ■ Helps prevent sunburn

Warnings

For external use only • Do not use on open wounds. • Stop use and ask physician if rash occurs. • **Keep out of reach of children.**

Directions

Apply generously to lips 15 minutes before sun exposure. • **For children under 6 months of age:** ask a doctor. • **Reapply:** As needed and at least every 80 minutes.



Manufactured for and distributed by:
Beauty by Earth • Flower Mound, TX 75028
www.beautybyearth.com
Certified to NSF / ANSI 305 by QAI

Drug Facts

Active Ingredients
Non-Nano Uncoated Zinc Oxide 10.5%
Purpose
Sunscreen



BEAUTY
BY EARTH®



SPF 15 Lip Balm
Piña Colada
MINERAL + REEF SAFE



Broad Spectrum & Water Resistant

0.15 oz e 4.25 g

PEEL BACK
FOR DRUG
FACTS

ARTWORK - INSIDE

Drug Facts (continued)

Inactive Ingredients

Helianthus Annuus (Sunflower) Seed Oil*, Beeswax*, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil*, Natural Flavor*, Polyhydroxystearic Acid, Butyrospermum Parkii (Shea) Butter*, Rubus Idaeus (Raspberry) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter*, Tocopherol (Sunflower Derived Vit E), Simmondsia Chinensis (Jojoba) Seed Oil*, Calophyllum Inophyllum (Tamanu) Seed Oil*
*Certified Organic Ingredients

ZINC OXIDE LIP BALM PINA COLADA

zinc oxide lip balm pina colada stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-226
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SHEA BUTTER (UNII: K49155WL9Y)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
COCOA BUTTER (UNII: 512OYT1CRR)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
.DELTA.-TOCOPHEROL (UNII: JU84X1II0N)	
TAMANU OIL (UNII: JT3LVK84A1)	
WHITE WAX (UNII: 7G1J5DA97F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	PINEAPPLE (Pina-colada)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-226-38	4.2 g in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final

part352

01/01/2020

Labeler - Private Label Select Ltd CO (005415463)

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Private Label Select Ltd CO