### SUNSCREEN- zinc oxide lip balm 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.

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## Soleil Toujours, Summer Camp Mineral BFF Lip Jam, SPF 15

## **Active Ingredient Section**

Active Ingredients	Purpose
Zinc Oxide 10.5%	Sunscreen

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, Simmondsia
Chinensis (Jojoba) Seed Oil\*, Calophyllum
Inophyllum (Tamanu) Seed Oil\* \*Certified
Organic Ingredient(s)

# **Indications and Usage**

**Uses** • Helps prevent sunburn • If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** Apply liberally on lips 15 minutes before sun exposure Reapply: • immediately after swimming, sweating or towel drying • at least every 2 hours • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 am—2 pm • Wear long-sleeved shirts, pants, hats, and sunglasses • Children under 6 months: Ask a doctor.

## Keep out of reach of children

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#### **Label Artwork**

Active Ingredient...Zinc Oxide 10.5% Inactive Ingredients...See Carton

Apply liberally on lips 15 minutes before sun exposure. Reapply at least every 2 hours. Refer to the box for ingredients, warnings, uses, directions, and other information.

Made in USA with globally sourced ingredients. ©2022 Summer Camp. Distributed by: Summer Camp, LLC, Lake Forest, IL 60045. Responsible Person: Biorius (EU 7170 Manage, Belgium; UK: London WC2H, 9JQ, Great Britain). 800-217-8552 / summercamplife.com Net Wt 0.15 oz (4.25 g)



#### **Unit Carton Artwork**



## SUNSCREEN

zinc oxide lip balm stick

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62932-267

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

.BETA.-TOCOPHEROL (UNII: 9U6A490501)

COCONUT OIL (UNII: Q9L0O73W7L)

Ingredient Name

Basis of Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)
ZINC OXIDE

10.5 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
SHEA BUTTER (UNII: K49155WL9Y)		
COCOA BUTTER (UNII: 5120YT1CRR)		
.ALPHATOCOPHEROL, D- (UNII: N9PR3490H9)		
.GAMMATOCOPHEROL (UNII: 8EF1Z1238F)		
WHITE WAX (UNII: 7G1J5DA97F)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
RASPBERRY SEED OIL (UNII: 9S8867952A)		
.DELTATOCOPHEROL (UNII: JU84X1IION)		
TAMANU OIL (UNII: JT3LVK84A1)		
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
IOIOBA OIL (UNII: 724GKU717M)		

Product Characteristics			
Color	white	Score	
Shape		Size	

Flavor	PINEAPPLE (Pina Colada) , COCONUT (Pina Colada)	Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932- 267-38	1 in 1 CARTON	05/05/2022	
1		4.2 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/05/2022	

# Labeler - Private Label Select Ltd CO (005415463)

Revised: 5/2022 Private Label Select Ltd CO