SUNSCREEN- zinc oxide sunscreen 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.

Olita Mineral Sunscreen Coco Bronze Tint, SPF 30

OTC-Active Ingredients

Active Ingredients
Zinc Oxide 20%

Dosage and Administration

Directions: Apply generously and evenly 15 minutes before sun exposure. Children under 6 months of age: Ask a doctor.

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 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- · at least every 2 hours

Inactive ingredients Caprylic/Capric Triglyceride*, Helianthus Annuus (Sunflower) Seed Oil*, Cera Alba (Beeswax)*. Euphorbia Cerifera (Candelilla) Wax. Copernicia Cerifera (Carnauba) Wax* Butyrospermum Parkii (Shea) Butter*, Ricinus Communis (Castor) Seed Oil*, Tocopherol, Theobroma Cacao (Cocoa) Seed Butter*, Aloe Barbadensis Leaf Juice (Aloe Vera) Powder*, Mica (Ci:77019,), Iron Oxídes (Ci:77492) (Ci:77491) (Ci:77499)

*Certified Organic Ingredients

Other Information: Protect the product in this container from excessive heat and direct sun

Indications & 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.

OTC-Purpose

Purpose Sunscreen

Warnings PART 1

Warnings: Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove.

Warnings Part Two

Drug Facts (continued)

Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

OTC Keep out of reach of children

Drug Facts (continued)

Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Back Label



Drug Facts (continued) Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical Hinge i help or contact a Poison Control Center right away. Directions: Apply generously and evenly 15 minutes before sun exposure. 0.125 Children under 6 months of age: Ask a doctor. Sun Protection Measures: Spending ı time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, Hing regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher ı = and other sun protection measures including: 0.125 limit time in the sun. especially from 10 a.m. - 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses Reapply: · after 80 minutes of swimming or sweating

Drug Facts (continued) · immediately after towel drying · at least every 2 hours Inactive ingredients Caprylic/Capric Triglyceride*, Helianthus Annuus (Sunflower) Seed Oil*, Cera Alba (Beeswax)*, Euphorbia Cerifera (Candelilla) Wax, Copernicia ı = Cerifera (Carnauba) Wax*, Butyrospermum Parkii (Shea) Butter*, Ricinus Communis (Castor) Seed Oil*, Tocopherol, Theobroma Cacao (Cocoa) 0.1 Seed Butter*, Aloe Barbadensis Leaf Juice (Aloe Vera) Powder*, Mica (Ci:77019), Iron Oxides (Ci:77492) (Ci:77491) (Ci:77499) Hing *Certified Organic Ingredients Other Information: = Protect the product in this container from excessive heat and direct sun. Distributed by OLITA Inc., ı San Rafael, CA, USA, 94903 Made in the USA olitashop.com Certified to NSF/ANSI 305 by QAJ

Front Label



SUNSCREEN

zinc oxide sunscreen stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOIZLOH54Z) (ZINC OXIDE - UNII:SOIZLOH54Z)	ZINC OXIDE	20 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
COCONUT OIL (UNII: Q9L0O73W7L)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
MICA (UNII: V8A1AW0880)		
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
COCOA BUTTER (UNII: 512OYT1CRR)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
.BETATO COPHEROL (UNII: 9 U6 A49 0 50 1)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)		
WHITE WAX (UNII: 7G1J5DA97F)		
CANDELILLA WAX (UNII: WL0328 HX19)		

Product Characteristics			
Color	brown (Medium Brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging				
ı	# Iten	n Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:62	932-215-33	14 g in 1 CONTAINER; Type 0: Not a Combination Product	02/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2020	

Labeler - Private Label Select Ltd CO (005415463)

Revised: 3/2020 Private Label Select Ltd CO