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 Light Tan Tint, SPF 30

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 drving
- at least every 2 hours

Warnings Section 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 Section 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.

Inactive Ingredients

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 Oxides (Ci:77492) (Ci:77491) (Ci:77499) *Certified Organic Ingredients

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.

OTC Purpose Section

Purpose Sunscreen

OTC Active Ingredient Section

Active Ingredients Zinc Oxide 20%

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.

Front Label



Back Label





limit time in the sun

Reapply:

especially from 10 a.m. - 2 p.m.

 wear long-sleeved shirts, pants, hats, and sunglasses

after 80 minutes of

swimming or sweating

0.125

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 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 Oxides (Ci:77492) (Ci:77491) Hing (Ci:77499) *Certified Organic Ingredients Other Information: Protect the product in this 0.125 container from excessive heat and direct sun. Distributed by OLITA Inc., San Rafael, CA, USA. 94903 Made in the USA olitashop.com Certified to NSF/ANSI 305 by QAJ

SUNSCREEN

zinc oxide sunscreen stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62932-214

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)ZINC OXIDE20 g in 100 g

Inactive Ingredients Ingredient Name Strength FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K) SHEA BUTTER (UNII: K49155WL9 Y) TOCOPHEROL (UNII: 80ZB2556P8) COCOA BUTTER (UNII: 512OYT1CRR) MICA (UNII: V8 A1AW0880) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) CARNAUBA WAX (UNII: R12CBM0EIZ) FERRIC OXIDE RED (UNII: 1K09F3G675) ALOE VERA LEAF (UNII: ZY81Z83H0X)

FERRO SO FERRIC O XIDE (UNII: XM0 M8 7F357)	
WHITE WAX (UNII: 7G1J5DA97F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CANDELILLA WAX (UNII: WL0328 HX19)	
CASTOR OIL (UNII: D5340 Y2I9G)	

Product Characteristics				
Color	brown (Light Tan)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

l	Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 N	NDC:62932-214-33	14 g in 1 CONTAINER; Type 0: Not a Combination Product	02/01/2020		

Marketing Info	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: 2/2020 Private Label Select Ltd CO