### SUNSCREEN- zinc oxide sunscreen ointment 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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### Suntegrity, Mineral Sun Stick, SPF 30 - Tinted Medium

## Drug Facts (cont...)

#### 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 Stop use and ask a doctor if rash occurs When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

■apply liberally 15 minutes before sun exposure ■Reapply: ■after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least every 2 hours ■ Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and skin ■

## Warnings

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## Drug Facts (cont...)

early 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: I limit time in the sun, especially from 10am to 2pm

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

children under 6 months; Ask a doctor

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 ingredient

Other Information:

protect this product from excessive heat & direct sun

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 ingredient

### **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

### Keep out of reach of children

## Warnings

- For External use only
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## OTC-Purpose Section

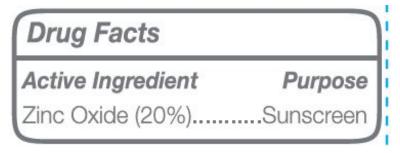
# **Drug Facts**

Active Ingredient

**Purpose** 

Zinc Oxide (20%).....Sunscreen

## **OTC-Active Ingredient Section**



### **Front Label**



#### **Back Label**







TOP TOP BACKSIDE BASE

#### **SUNSCREEN**

zinc oxide sunscreen ointment

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:62932-218

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 20 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
.BETATO CO PHERO L (UNII: 9 U6 A49 0 50 1)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
.ALPHATO COPHERO L, D- (UNII: N9 PR349 0 H9)		
.GAMMATO CO PHERO L (UNII: 8 EF1Z1238 F)		
MICA (UNII: V8A1AW0880)		
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
.DELTATO COPHERO L (UNII: JU8 4X1II0 N)		
COCOA BUTTER (UNII: 5120 YT1CRR)		
WHITE WAX (UNII: 7G1J5DA97F)		
CANDELILLA WAX (UNII: WL0328HX19)		

FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	bro wn	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging						
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>		
1 NI	OC:62932-218-26	46 g in 1 TUBE; 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)

## Registrant - Private Label Select Ltd CO (005415463)

Revised: 7/2020 Private Label Select Ltd CO