

**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.*

**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: ▪ 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***

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- Stop use and ask a doctor if rash occurs
- When using this product keep out of eyes. Rinse with water to remove.
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### **OTC-Purpose Section**

#### ***Drug Facts***

<b><i>Active Ingredient</i></b>	<b><i>Purpose</i></b>
Zinc Oxide (20%).....	Sunscreen

**OTC-Active Ingredient Section**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Zinc Oxide (20%).....	Sunscreen

**Front Label**



## Back Label

MEDIUM

Distributed By  
Suntegrity Skincare®  
Las Vegas, NV 89128  
Certified To NSF / ANSI 305 by QAI

**Drug Facts**

Active Ingredient	Purpose
Zinc Oxide (20%).....	Sunscreen

www.SuntegritySkincare.com

PRODUCED IN THE USA

PEEL HERE

TOP

**Drug Facts (cont...)**

**Uses**

- helps Prevent Sunburn
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**Warnings**

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**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

TOP BACKSIDE

**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:

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**Other Information:**

- protect this product from excessive heat & direct sun

BASE

## SUNSCREEN

zinc oxide sunscreen ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62932-218
<b>Route of Administration</b>	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
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
CASTOR OIL (UNII: D5340Y2I9G)	
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
MICA (UNII: V8A1AW0880)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.DELTA.-TOCOPHEROL (UNII: JU84X1IIN)	
COCOA BUTTER (UNII: 512OYT1CRR)	
WHITE WAX (UNII: 7G1J5DA97F)	
CANDELILLA WAX (UNII: WL0328HX19)	

<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

<b>Product Characteristics</b>			
<b>Color</b>	brown	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-218-26	46 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2020	

<b>Marketing Information</b>			
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)