

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.

Suntegrity, Mineral Sun Stick, SPF 30 - Tinted Light

ACTIVE INGREDIENTS

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

DOSAGE AND ADMIN.

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 ▶

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 INGREDIENT

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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

OTC- KEEP OUT OF REACH

Warnings

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OTC-PURPOSE

Drug Facts

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

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 SECTION

Warnings

- For External use only
- Do not use on damaged or broken skin
- Stop use and ask a doctor if rash occurs
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BACK LABEL

LIGHT

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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- Stop use and ask a doctor if rash occurs
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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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- wear long-sleeved shirts, pants, hats, and sunglasses
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Other Information:

- protect this product from excessive heat & direct sun

BASE

FRONT LABEL



SUNSCREEN

zinc oxide sunscreen stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-219
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
COCOA BUTTER (UNII: 512OYT1CRR)	
CASTOR OIL (UNII: D5340Y2I9G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.DELTA.-TOCOPHEROL (UNII: JU84X1H0N)	
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
WHITE WAX (UNII: 7G1J5DA97F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SHEA BUTTER (UNII: K49155WL9Y)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	

Product Characteristics

Color	brown (Light Brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-219-26	46 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)