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.

Rinse Bath & Body SPF 30 Unscented Sunstick

OTC - ACTIVE INGREDIENT SECTION



OTC - KEEP OUT OF REACH OF CHILDREN

skin rash occurs. **Keep out of reach of children.**If product is swallowed,
get medical help or
contact a Poison Control
Center right away.

OTC - PURPOSE



ARTWORK (BACK LABEL NO. 1)

Drug Facts

Active Ingredients

Zinc Oxide 20%

Purpose Sunscreen

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

Inactive Ingredients

Aloe Barbadensis Leaf Juice Powder*, Beeswax*, Candelilla Wax, Carnauba Wax*, Castor Seed Oil*, Cocoa Seed Butter*, Coconut Oil*, Shea Butter*, Sunflower Seed Oil*, Tocopherol (*Certified Organic Ingredient(s))



ARTWORK (BACK LABEL NO. 2)

Drug Facts (continued)

Warnings

For External Use Only.
Do not use on damaged or broken skin. When using this product: keep out of eyes. Rinse with water to remove. Stop use and ask doctor if skin rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • Reapply: after 80 minutes of swimming or sweating & immediately after towel drying at least every 2 hours. • Children under 6 months: ask doctor.• Sun Protection Measures: spending time in the sun

increases your risk of skin

ARTWORK (FRONT LABEL)

0.125 " Hing

25 " Hinge



ARTWORK (BACK LABEL NO. 3)

25 " Hinge

" Hind

Drug Facts (continued)

Directions continued

cancer and early skin aging. To decrease this risk, regularly use a sunscreen with 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-sleeve shirts, pants, hats, and sunglasses.

Other Information

Protect this product from excessive heat and sun.

DISTR. RINSE BATH & BODY
106 SOUTH BROAD STREET
MONROE, GA 30655
678.525.1927
CERTIFIED TO THE
NSF/ANSI 305 BY QAI

SUNSCREEN

zinc oxide sunscreen stick

Route of Administration

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-243

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	
SUNFLOWER OIL (UNII: 3W1JG795YI)		
.ALPHATO COPHEROL, D- (UNII: N9 PR349 0 H9)		
COCONUT OIL (UNII: Q9L0O73W7L)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
.GAMMATO COPHEROL (UNII: 8EF1Z1238F)		
.DELTATO COPHEROL (UNII: JU84X1II0N)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
WHITE WAX (UNII: 7G1J5DA97F)		
CANDELILLA WAX (UNII: WL0328 HX19)		
COCOA BUTTER (UNII: 512OYT1CRR)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
.BETATO COPHEROL (UNII: 9 U6 A49 0 50 1)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1	NDC:62932-243-42	18 g in 1 CONTAINER; Type 0: Not a Combination Product	0 1/0 1/20 20	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/0 1/20 20	

Labeler - Private Label Select Ltd CO (005415463)

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