

TINTED SUNSCREEN- tinted 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.

Protekt Tinted SPF 30 Mineral Sunscreen

OTC Active Ingredient Section

<h1>Drug Facts</h1>
<h2>Active Ingredient</h2>
Zinc Oxide 20%

OTC Keep out of reach of children

<h3>Warnings</h3>
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.

OTC Purpose

<h1>Purpose</h1>
Sunscreen

ARTWORK (FRONT)



ARTWORK (BACK)

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 20%	Sunscreen
Uses: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin aging caused by the sun.	

PROTEKT PRODUCTS INC.
 30 N GOULD ST, SUITE 4095
 SHERIDAN, WY 82801
 CERTIFIED NSF/ANSI
 305 BY QAI



 MADE IN THE USA

Drug Facts (continued)	
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(s))	
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.	

0.125 " Hinge

Drug Facts (continued)	
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 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 10am - 2pm. Wear long-sleeve shirts, pants, hats, and sunglasses.	
Other Information	
Keep this product away from excessive heat and sun.	

0.125 " Hinge

TINTED SUNSCREEN

tinted zinc oxide sunscreen stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-240
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
WHITE WAX (UNII: 7G1J5DA97F)	
CANDELILLA WAX (UNII: WL0328HX19)	
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
.DELTA-TOCOPHEROL (UNII: JU84X1H0N)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CASTOR OIL (UNII: D5340Y2I9G)	
MICA (UNII: V8A1AW0880)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-240-34	14 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)