

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.

Sky Organics Mineral Sunscreen SPF50 177g

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Drug Facts

Active ingredient	Purpose
Zinc Oxide 25%	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

Warnings
 For external use
 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 a doctor if rash occurs
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 • Shake well. Apply liberally and evenly 15 minutes before sun exposure
 • Children under 6 months: ask a 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 a 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-sleeved shirts, pants, hats and sunglasses
 • Reapply: • after 80 minutes of swimming or sweating
 • immediately after towel drying
 • at least every 2 hours

Other information
 • protect the product in this container from excessive heat and direct sun

Inactive ingredients
 Helianthus Annuus (Sunflower) Seed Oil* • Cocos Nucifera (Coconut)* Oil • Cera Alba (Beeswax) • Ricinus Communis (Castor) Seed Oil* • Rubus Idaeus (Red Raspberry) Seed Oil • Butyrospermum Parkii (Shea)* Butter • Prunus Armeniaca (Apricot) Kernel Oil* • Argania Spinosa (Argan) Kernel Oil* • Rosa Canina (Rosehip) Fruit Oil* • Tocopherol (Vitamin E) • *Certified Organic Ingredient

SUNSCREEN			
zinc oxide sunscreen ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ARGAN OIL (UNII: 4V59G5UW9X)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SHEA BUTTER (UNII: K49155WL9Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-185-30	177 g in 1 TUBE; Type 0: Not a Combination Product	11/29/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/29/2018	

Labeler - Private Label Select Ltd CO (005415463)**Registrant** - Private Label Select Ltd CO (005415463)