

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.

earth mama Baby Mineral Sunscreen SPF40 Lotion

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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 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.

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 product is swallowed, get medical help or contact Poison Control Center right away.

Directions ■ Apply generously and evenly to all skin exposed to sun 15 minutes before sun exposure ■ Children under 6 months of age: 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 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours

Drug Facts (continued)

Other Information ■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride (Fractionated Coconut), Cera Alba (Beeswax), Olea Europaea (Olive) Fruit Oil, Rubus Idaeus (Red Raspberry) Seed Oil, Punica Granatum (Pomegranate) Seed Oil, Simmondsia Chinensis (Jojoba) Oil, Butyrospermum Parkii (Shea) Butter, Tocopherol, Calendula Officinalis Flower (Calendula) Flower Extract *Organic

Questions or comments?
503-607-0607 or earthmamaorganics.com

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OTCO
L10-422-00

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SUNSCREEN

zinc oxide sunscreen ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-170
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
COCONUT OIL (UNII: Q9L0O73W7L)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	

RASPBERRY SEED OIL (UNII: 9S8867952A)	
SHEA BUTTER (UNII: K49155WL9Y)	
PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-170-20	84 g in 1 TUBE; Type 0: Not a Combination Product	12/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/31/2018	

Labeler - Private Label Select Ltd CO (005415463)

Registrant - Private Label Select Ltd CO (005415463)