SURYA NATURAL MINERAL SUNSCREEN- zinc oxide cream Hale Cosmeceuticals

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.

Surya Natural Mineral Sunscreen

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.

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 • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours • 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.

Other Information

• protect this product from excessive heat and direct sun • may stain some fabrics.

Inactive Ingredients

• Caprylic/Capric Triglyceride, Persea Gratissima (Avocado) Oil, Beeswax, Cocos Nucifera (Coconut) Oil, Soybean Glycerides, Shea Butter Unsaponificables, Tocopheryl Acetate, Bisabolol, Butyrospermum Parkii (Shea) Butter, Sesamum Indicum (Sesame) Seed Oil, Emblica Officinalis Fruit Extract, Curcumin, Copernicia Cerifera (Carnauba) Wax, Tetrahydrodiferuloylmethane, Tetrahydrodemethoxydiferuloylmethane, Tetrahydrobisdemethoxydiferuloylmethane, Potassium Cocoate, Tetrahexyldecyl Ascorbate, Fragrance.

Questions or comments?

Visit www.hncproducts.com or call 309-319-2151.

Package Labeling:

Broad Spectrum: SPF-35



e 30 ml. / 1 fl.oz

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Ouestions or comments

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Distributed By Hale Cosmeceuticals Bloomington, IL 61704

SURYA NATURAL MINERAL SUNSCREEN

zinc oxide cream

Product Information

Do not use if seal around cap is broken or missing.

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71987-009

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	200 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
AVOCADO OIL (UNII: 6VNO72PFC1)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
COCONUT OIL (UNII: Q9L0O73W7L)			
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
LEVOMENOL (UNII: 24WE03BX2T)			
SHEA BUTTER (UNII: K49155WL9Y)			
SESAME OIL (UNII: QX10HYY4QV)			
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)			
CURCUMIN (UNII: IT942ZTH98)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)			
TETRAHYDRODEMETHOXYDIFERULOYLMETHANE (UNII: 44D8X9U00T)			
TETRAHYDROBISDEMETHOXYDIFERULOYLMETHANE (UNII: 973IBV8W7I)			
POTASSIUM COCOATE (UNII: F8U72V8ZXP)			
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)			

Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71987- 009-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2022	12/31/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/01/2022	12/31/2024	

Labeler - Hale Cosmeceuticals (168405822)

Revised: 11/2022 Hale Cosmeceuticals