

TROPICAL TOPICAL MATTE SPF30- zinc oxide cream

Allure Labs

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.

Drug Facts

ACTIVE INGREDIENTS:

Zinc Oxide - 18.6 %

Purpose: Sunscreen

Uses: Helps prevent sunburn. If used as directed with other sun protection measures, this product decreases the risk of skin cancer and early skin aging caused by the sun.

Warning:

For external use only

Do not use on damage or broken skin.

When using this product keep out of eye. 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 a poison control center right away.

Direction:

Apply liberally 15 minutes before sun exposure.

Children under 6 month of age: Ask a doctor

Reapply at least every 2 hours.

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 am - 2.0 pm, Wear long - sleeved shirts, pants, hats and sunglasses.

Other Information:

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

INACTIVE INGREDIENT: Water, Cyclopentasiloxane, Butylene Glycol, Glycerin, Cyclohexasiloxane, Glyceryl Stearate, PEG-100 Stearate, Polyglyceryl-3 Polydimethylsiloxyethyl, Dimethicone, Sorbitan Stearate, Cetyl Alcohol, Teprenone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Caprylic/Capric Triglyceride, Imperata Cylendrica Root Extract, Arabidopsis Thaliana Extract, Plankton Extract, Micrococcus Lysate, Phoenix Dactylifera (Date) Fruit Extract, Polygonum Aviculare Extract, Sodium Lactate, Lecithin, Dipotassium Glycyrrhizate, Tocopheryl Linoleate/ Oleate, Citric Acid, Polyacrylamide, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerine, Hexylene Glycol, Xanthan Gum, C13-14 Isoparaffin, Laureth-7, PEG-

8, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Fragrance, Disodium EDTA.

<p>SORELLA APOTHECARY</p> <p>DRUG FACTS</p> <p>Active Ingredient: Zinc Oxide 18.6 % Purpose: Sunscreen</p> <p>Uses: • Helps prevent tanlines • If used in concert with other sun protection measures, this product decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p>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 contact is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions: • Apply liberally 15 minutes before sun exposure. • Children under 6 months of age Ask a doctor. • Reapply at least every 2 hours.</p> <p>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. to 2 p.m. • Wear long-sleeved shirts, pants, hats and sunglasses.</p> <p>Other Information: Protect the product in this container from excessive heat and direct sun.</p> <p>Inactive Ingredients: Water, Glycerin/Propylene Glycol, Stearic Acid, Cellulose Acrylate, Ethyl Stearate, PEG-100 Stearate, Polyglyceryl-3 Polydimethylsiloxyl Dimethicone, Sorbitol Stearate, Dimethicone, Cetyl Alcohol, Squalene, Carbonyl Diethyl Dimethicone, Caprylic/Capric Triglyceride, Inositol (vitamin B6) Extract, Arabidopsis Thaliana Extract, Phloxin Extract, Alnus Incana Bark, Phloxin (Date) Fruit Extract, Polyglyceryl-3 Stearate, Sodium Lauryl Sulfate, Dimethyl Glycolate, Tocopheryl Acetate/Glycol, Citric Acid, Polysorbate 80, Phenoxyethanol, Glycerin Ethylhexyl Stearate, PEG-4, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Fragrance, Disodium EDTA.</p> <p>   </p> <p>SORELLAAPOTHECARY.COM Sorella Apothecary, Reno, NV 89521</p>	<p>HOW TO USE</p> <p><i>Apply to cleansed and toned face and neck every morning</i></p> <p><i>Re-apply every 2 hours when exposed to sun or as needed.</i></p>	<p>SORELLA APOTHECARY</p> <p><i>Tropical Topical</i></p> <p>MATTE SPF</p> <p><i>SPF 30 keeps skin safe and shine-free in the sun</i></p> <p>2 OZ / 57 G</p>	<p>DESCRIPTION</p> <p><i>A sweet treat for the beach and every day—SPF 30 protects you from UVA and UVB rays, while keeping skin smooth, hydrated and matte.</i></p>
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TROPICAL TOPICAL MATTE SPF30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4231
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
POLYACRYLAMIDE (CROSSLINKED; 2 MOLE PERCENT BISACRYLAMIDE) (UNII: 9FPL31B58Q)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TRIETHOXYSIYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
DATE (UNII: H3O7QI5HY7)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LAURETH-7 (UNII: Z95S6G8201)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
TEPRENONE (UNII: S8S8451A4O)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4231-2	1 in 1 CARTON	08/23/2023	
1	NDC:62742-	57 q in 1 TUBE; Type 0: Not a Combination		

4231-1	Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/23/2023	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment			
Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4231)

Revised: 8/2023

Allure Labs