BROAD SPECTRUM SPF30 MINERAL SUNSCREEN- 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 (non-nano) 21 %

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.

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 swadlowed get medical help or contact a poison control center right away

Directions

Shake well before use

Apply generously 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water-resistant sunscreen if swimming or sweating

Sun Protection Measures. Spending lime in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with abroad Spectrum SPF value of 15 or higher and other sun protet-Wn measures including

Limit time in the sun, especial& from 10 arn.-2 p.m

Wear long-sleeved shirts, pants, hats and sunglasses

Children under 6 months of age Ask a doctor.

Other information

i.

Protect the product in this conitainer from excessive heat and direct sun May stain some fabrics Inactive Ingredients Water (Aqua) Caprylic/Capric Triglyceride Coconut Alkanes Cetearyl Alcohol Glycerin Coco-Glucoside Squalane Butyrospermum Parkii Nut Extract Aloe Barbadensis Leaf Juice Cetearyl Glucoside Coco-Caprylate/Caprate Caprylyl/Capryl Glucoside Hydrolyzed Jojoba Esters Cucumis Sativus (Cucumber) Fruit Extract sr-Hydrozoan Polypeptide-1 Polyhydroxystearic Acid Polyglyceryl-3 Polyricinoleate Isostearic Acid Lecithin SodiuM Ascorbyl Phosphate Sclerotium Gum Xanthan Gum Ethylhexylglycerin Sodium Phytate **Tocopheryl Acetate** Phenoxyethanol Sodium Benzoate



BROAD SPECTRUM SPF30 MINERAL SUNSCREEN

zinc oxide cream

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:62742-4209		
Route of Administration TOPICAL						
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Stren	ngth	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE		21 g in 100 g	

	Ingredient Name	Ingredient Name		
COCO GLUCOSIDE (UNII: ICS790225B)				
SHEANUT (UNII: 84	H6HBP32L)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
COCO-CAPRYLATE	CAPRATE (UNII: 8D9H4QU99H)			
CAPRYLYL/CAPRYI	OLIGOGLUCOSIDE (UNII: E00JL9G9K0)			
SODIUM ASCORB	(L PHOSPHATE (UNII: 836SJG51DR)			
BETASIZOFIRAN (U	JNII: 2X51AD1X3T)			
XANTHAN GUM (UI	JII: TTV12P4NEE)			
HYDROLYZED JOJO	DBA ESTERS (ACID FORM) (UNII: UDR641JW	8W)		
CUCUMBER (UNII:)	YY7C30VXJT)			
POLYHYDROXYST	EARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
LECITHIN, SOYBE	AN (UNII: 1DI56QDM62)			
CETOSTEARYL AL	COHOL (UNII: 2DMT128M1S)			
GLYCERIN (UNII: PE	DC6A3C0OX)			
PHYTATE SODIUM	(UNII: 88496G1ERL)			
ALPHATOCOPHE	ROL ACETATE (UNII: 9E8X80D2L0)			
PHENOXYETHANO	L (UNII: HIE492ZZ3T)			
SODIUM BENZOAT	re (UNII: OJ245FE5EU)			
ETHYLHEXYLGLYC	ERIN (UNII: 147D247K3P)			
CETEARYL GLUCO	SIDE (UNII: 09FUA47KNA)			
COCONUT ALKAN	ES (UNII: 1E5KJY107T)			
POLYGLYCERYL-3	PENTARICINOLEATE (UNII: 7Q00K5D0T4)			
SQUALANE (UNII: G	W89575KF9)			
WATER (UNII: 059Q	F0KO0R)			
MEDIUM-CHAIN TI	RIGLYCERIDES (UNII: C9H2L21V7U)			
ISOSTEARIC ACID	(UNII: X33R8U0062)			
Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part352	03/24/2022	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4209)

Revised: 3/2022

Allure Labs