PROTECT BROAD SPECTRUM SPF 30- zinc oxide cream Allure Labs Inc

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 Ingredient:

Zinc Oxide - 18.9%

Purpose: Sunscreen

Uses:

- Helps prevent sunburn.
- If used as directed with other sun protection measures, 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 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 a Poison Control right away.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply: after swimming or sweating. Immediately after towel drying. 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 of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10am 2pm.
- wear long sleeves shirts, pants, hats and sunglasses.
- Children under 6 months: Ask a doctor.

Protect this product from excessive heat and direct sun.

Email; info@aoskincare.com or call (415)653-3939

Caprylic/Capric Triglyceride, Water (Aqua), Glycerin, Polysorbate 60, Stearic Acid, Cetyl Alcohol, Sorbitan Stearate, Cetearyl Glucoside, Stearic Acid, Polyhydroxystearic acid, Polyglyceryl-3 Polyricinoleate, Isosrearic Acid, Lecithin, Cetyl Alcohol, Lanolin, Aloe Barbadensis Leaf Juice, Phomium Tenax Seed Oil, Stearyl Alcohol, Gardenia Jasminoides Meristem Cell Culture, Niacinamide, Prunus Amygdulus Dulcis (Sweet Almond) Oil, Honey, Tocopherol, Totarol, Ferulic Acid, Disodium EDTA, Xanthan Gum, Carageenan, Punica Granatum Extract, Dihydroacetic Acid, Corn Starch Modified, Benzyl Alcohol, Astaxanthin.

Distributed by Distil Skincare LLC

Mailing address: Swapbox ATUP1-1T5DK,

880 Peru Ave #2, San Francisco 94112, USA



PROTECT BROAD SPECTRUM SPF 30

zinc oxide cream

Product Information	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4166		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	189 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)	
CETEARYL GLUCO SIDE (UNII: 09 FUA47KNA)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
ALOE (UNII: V5VD430 YW9)	
PHORMIUM TENAX SEED OIL (UNII: OZ80CEA779)	
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	
GARDENIA CORNUTA WHOLE (UNII: 0WC27VVS87)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PRUNUS AMERICANA FRUIT (UNII: 3F57WKW68K)	
HO NEY (UNII: Y9 H1V576 FH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TOTAROL (UNII: 67NH2854WW)	
FERULIC ACID (UNII: AVM951ZWST)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARRAGEENAN (UNII: 5C69 YCD2YJ)	
PUNICA GRANATUM FLO WER (UNII: D9B634V4GP)	
CORN STARCH 3-E-DO DECENYL SUCCINIC ANHYDRIDE MO DIFIED (UNII: QG4MW19 XYX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ASTAXANTHIN (UNII: 8 XPW32PR7I)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4166-2	1 in 1 CARTON	02/09/2018	
1	NDC:62742-4166-1	59 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/09/2018	

Labeler - Allure Labs Inc (926831603)

Revised: 2/2018 Allure Labs Inc