

FLORIDA GLOW SPF 30- zinc oxide lotion
Southeast Holdings Corp.

Active Ingredients

Zinc Oxide 14.6%

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.

Stop use and ask a doctor if rash occurs.

Do not use on damaged or broken skin.

When using this product Keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure

- Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- 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 Broad Spectrum 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 sleeve shirts, pants, hats & sunglasses

Inactive Ingredients

Triethoxycaprylsilane, Water, Coco-Caprylate/Caprate, Isoamyl laurate, Glycerine, Polyglyceryl -6 Stearate, Jojoba Oil, Propanediol, Shea Butter, Xanthum

Gum, Phenoxyethanol, Green Tea Leaf Extract, Cetyl Alcohol, Silica, Polyhydroxystearic Acid, Pongomia Pinnata Seed Extract, Sphingomonas Ferment Extract, Aloe Barbadensis Leaf Extract, Lecithin, Sclerotium Gum, Pullulan, Ethylhexylglycerin

Other Information

- Protect this product from heat and direct sun.
- May stain or damage some fabrics or surfaces.

Questions or Comments?

Call 1 (800) 931-9254

Product label

SPF 30

FACE + BODY

100% MINERAL SUNSCREEN LOTION

BROAD SPECTRUM SPF 30
WATER RESISTANT
SWEAT RESISTANT
(80 MINUTES)

GREEN TEA EXTRACT

Anti-Aging Ferment Extract
No SPF Boosters
Fragrance free

reef-friendly

3.4 FL OZ / 100 ml

Drug Facts

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Water, Coco-Caprylate/Caprate, Isocetyl Laurate, Glycerin, Propanediol, Shea (Butyrospermum Parkii) Butter, Jojoba (Simmondsia Chinensis) Seed Oil, Polyglyceryl-6 Stearate, Polyglyceryl-6 Behenate, Aloe Barbadensis Leaf Extract, Green Tea (Camellia Sinensis) Leaf Extract, Sphingomonas Ferment Extract, Pongamia Pinnata Seed Extract, Xanthan Gum, Cetyl Alcohol, Silica, Lethitin, Scheritolium Gum, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Puhulan, Phenoxylethanol, Ethylhexylglycerin

Questions or Comments?
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Proudly made in South Florida, U.S.A.
Distributed by Southeast Holdings Corp., dba Florida Glow, Boca Raton, FL 33433
www.FloridaGlow.com

FLORIDA GLOW SPF 30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83862-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	14.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
JOJOBA OIL (UNII: 724GKU717M)	
PROPANEDIOL (UNII: 5965N8W85T)	
SHEA BUTTER (UNII: K49155WL9Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
SPHINGOFUNGIN C (UNII: S0392RT2G8)	
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83862-005-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	01/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/19/2021	

Labeler - Southeast Holdings Corp. (122400191)

Establishment

Name	Address	ID/FEI	Business Operations
Southeast Holdings Corp		080504027	manufacture(83862-005) , label(83862-005) , pack(83862-005)