

FLORIDA GLOW FACE SHIELD SPF 55- homosalate, octocrylene, zinc oxide lotion
Southeast Holdings Corp.

Active Ingredients

Homosalate 10%
Octocrylene 5%
Zinc Oxide 5.8%

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 or irritation develops and lasts.

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, Ethylhexyl Stearate, Isopropyl Palmitate, Helianthus Annus (Sunflower) Seed Oil, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone, Hydrogenated Polyisobutene , Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Methylisothiazolinone, Caprylyl Glycol, Sodium Chloride, Cyclopentasiloxane, Cyclohexasiloxane, Hydrogenated Castor Oil, Aloe Barbadensis Leaf Extract, Silica, Polyglyceryl-3 Oleate

Other Information

- protect this product from heat and direct sun.

Questions or Comments?

Call 1 (754) 214-9379

Product label

Face Shield

SPF 55

 UVA-UVB PROTECTION

WATER AND SWEAT RESISTANT (80 MINS)

Ultra Lightweight
Fragrance Free
Non-Comedogenic



NET WT 70 ML

Drug Facts		
Active Ingredients		Purpose
Homosalate	10.0% w/w	Sunscreen
Zinc Oxide	5.7% w/w	Sunscreen
Octocrylene	5.0% w/w	Sunscreen
Uses		
<ul style="list-style-type: none"> Helps prevent sunburn If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun 		
Warnings		
For external use only		
Do not use on damaged or broken skin		
When using this product		
<ul style="list-style-type: none"> Keep out of eyes. Rinse with water to remove 		
Stop use and ask doctor if		
<ul style="list-style-type: none"> Rash or irritation develops and lasts 		
Keep out of reach of children		
<ul style="list-style-type: none"> If product is swallowed, get medical help or contact a Poison Control Center right away. 		
Directions:		
<ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure Reapply: <ul style="list-style-type: none"> After 80 minutes of 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 broad spectrum SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long sleeve shirts, pants, hats, and sunglasses Children under 6 months: Ask a doctor 		
Other Information		
Protect this product from excessive heat and direct sun.		
Inactive ingredients		
Water, Hydrogenated Polyisobutene, Aloe Barbadensis Leaf Extract, Ethylhexyl Stearate, Cyclopentasiloxane, Isopropyl Palmitate, Sunflower (Helianthus Annuus) Seed Oil, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cyclohexasiloxane, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone, Hydrogenated Castor Oil, Polyglyceryl-3 Oleate, Silica, Methylisothiazolinone, Triethoxycaprylylsilane, Caprylyl Glycol, Sodium Chloride		
Questions or comments call?		
Call 1 (754) 214-9379		

Distributed By
Southeast Holdings Corp.
dba Florida Salt Scrubs,
Boca Raton, FL 33433
www.FloridaGlow.com



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FLORIDA GLOW FACE SHIELD SPF 55

homosalate, octocrylene, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83862-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SUNFLOWER OIL MONOGLYCERIDES (UNII: ZVW8EIZ3IE)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
HYDROGENATED POLYISOBUTENE (450 MW) (UNII: 7YR4ZFS62E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYGLYCERYL-3 OLEATE (UNII: XRQ165498B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83862-004-01	70 mL in 1 BOTTLE; 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(83862-004) , label(83862-004) , pack(83862-004)