CAY SKIN ISLE GLOW FACE SPF 45- avobenzone, octisalate, octocrylene lotion Cay Skin, 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.

Cay Skin Isle Glow Face Lotion SPF 45

Drug Facts

Active ingredients

Avobenzone 3%, Octisalate 5%, Octocrylene 10%

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 eyes. Rinse with water to remove.

Stop use and consult a doctor

if skin rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Adults and children over 6 months of age:

- Apply liberally 15 minutes before sun exposure.
- Reapply: at least every 2 hours; immediately after towel drying.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: 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 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. - 2 p.m.; wear long-sleeved shirts, pants, hats and sunglasses.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Water, Butyloctyl Salicylate, Sodium Potassium Aluminum Silicate, Diisopropyl Sebacate Diisopropyl Adipate, C12-15 Alkyl Benzoate, Lauryl Lactate, Glycerin, Mica, Propanediol, Glyceryl Stearate, Citrullus Lanatus (Watermelon) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Lens Esculents (Lentil) Fruit Extract, Chondrus Crispus Extract, Panthenol, Niacinamide, Ferulic Add, Helianthus Annuus (Sunflower) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Cetyl Phosphate, Glyceryl Stearate Citrate, Silica, Caprylyl Glycol, 1,2-Hexanediol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Chlorphenesin, Aminomethyl Propanol, Disodium EDTA, Sodium Lactate, Sodium PCA, Vanilla Planifolia Fruit Extract, Santalum Album (Sandalwood) Oi, Rosa Damascena Flower Oil, Myroxylon Pereirae (Balsam Peru) Oil, Cupressus Sempervirens Leaf/Nut/Stem Oil, Coffea Arabica (Coffee) Seed Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Aurantium Amara (Bitter Orange) Flower Oil, Amyris Balsamifera Bark Oil, Sodium Benzoate, Potassium Sorbate, Caprylic/Capric Triglyceride, Limonium Gerberi Extract, Limonene, Linalool, Benzyl Benzoate, Titanium Dioxide, Iron Oxides

Questions or comments?

cayskin.com (256) 396-8268

Product Packaging

MADE WITH CLEAN SKINCARE ACTIVES AND ISLAND-BASED

CAY SIGNATURE INGREDIENTS

Sea Moss: A nutrient-rich and protect the skin's

Hydrating Nectar:

Niacinamide/Vitamin B3: and smoothes the skin

Panthenol/Vitamin B5:

NO COMPROMISES

CLEAN SUNSCREEN ACTIVES, REEF-SAFE*, DERMATOLOGIST TESTED, NON-COMEDOGENIC, NO SYNTHETIC FRAGRANCE, VEGAN, CRUELTY-FREE, SULFATE, PARABEN AND SILICONE-FREE

*DOES NOT CONTAIN OXYBENZONE OR OCTINOXATE

CAY SKIN



SPF 45

45 ML — 1.5 FL OZ US

and antioxidant-packed face

For daily use with or

CAY SKIN was created for everyone under the sun to love their skin — everyday,

Our products are formulated effective skincare-grade

CAY ® SKIN — MADE IN USA FROM GLOBALLY SOURCED MATERIALS Distributed by Skinasum, Inc., Miamu, Fl. 33140 Cayskin.com Caxf6s dir.c



Drug Facts

Active ingredients (w/w) Purpose

USES • Helps prevent suntum • 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 eyes. Rinse with water

Stop use and consult a doctor if skin resh occurs.

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

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Discopropyl Sebacate Discopropyl Adepte, C12-15 Alkyl Benzeate,
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Larryl Laztae, Glycein, Mica, Prepanediol, Gyceryl Stearate, Citrollus
Landins Watermelson Frair Extract, Chondrus Crispus Extract,
Pamtheriol, Nacionamide, Francic Aod, Heisemitus Annus Spunitiower)
Seed Oll, Theobroma Cazao (Ozora) Seed Butter, Centy Phosphate,
Glyceryl Stearate Citrate, Silica, Caprylyl Glycol, 1,2-Hezanediol,
Arrylates/C10-30 Alkyl Acrylate Crosspolymer, Chlorybraesis,
Amriomethyl Proparol, Bisodium EDIA, Sodium Lactate, Sodium PCA,
Vanita Planfolia Frair Extract, Santalum Album (Santalywood), Nesso Burrassorae Rivers (Dil, Mycorylon Pereirae, Glatson Pengl Gil,
Cyrresses Sempervierus Leaf/Mur/Seen Ol, Coffee Analica; (Coffee)
Seed Oli, Citrus Arrantium Bergamia (Bergamod) Frui Oli, Citrus
Aurantium Amara (Bitter Change) Flower Di, Amyris Balsamifera Bark
Di, Sodium Berozete, Potassium Schoele, Caprylor/Capric Triglyceride,
Limonium Gerberi Extract, Limonena, Linalod, Benzyl Bercnete,
Titanium Disords, Inn Obdies

Questions or comments?

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CAY SKIN ISLE GLOW FACE SPF 45

avobenzone, octisalate, octocrylene lotion

Product Information

HUMAN OTC DRUG NDC:82657-002 **Product Type** Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
CHONDRUS CRISPUS (UNII: OQS23HUA1X)		
PANTHENOL (UNII: W9CM0O67Z)		

NIACINAMIDE (UNII: 25X51I8RD4) SUNFLOWER OIL (UNII: 3W1|G795YI) COCOA BUTTER (UNII: 5120YT1CRR) CETYL PHOSPHATE (UNII: VT07D6X670) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) CHLORPHENESIN (UNII: 1670DAL4SZ) FERRIC OXIDE RED (UNII: 1K09F3G675) FERRIC OXIDE YELLOW (UNII: EX43802MRT) LIMONENE, (+/-)- (UNII: 9MC3I34447) AMYRIS BALSAMIFERA OIL (UNII: 11B|961|2E) BALSAM PERU OIL (UNII: DIK0395679) 1,2-HEXANEDIOL (UNII: TR046Y3K1G) **EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) SODIUM LACTATE (UNII: TU7HW0W0QT)** SANDALWOOD OIL (UNII: X7X01WMQ5F) ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) LIMONIUM GERBERI WHOLE (UNII: 2|5K7YCF9F) BENZYL BENZOATE (UNII: N863NB338G) FERROSOFERRIC OXIDE (UNII: XM0M87F357) **SODIUM PYRROLIDONE CARBOXYLATE** (UNII: 4690TG57A2) VANILLA (UNII: Q74T35078H) ARABICA COFFEE OIL (UNII: IK55HKE887) **BERGAMOT OIL (UNII: 39W1PKE3II) BITTER ORANGE OIL** (UNII: 9TLV70SV6I) **CUPRESSUS SEMPERVIRENS WHOLE (UNII: VOIW9P606)) SODIUM BENZOATE** (UNII: O|245FE5EU) LAURYL LACTATE (UNII: G5SU0BFK7O) **GLYCERIN** (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KO0R) **BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)** DIISOPROPYL SEBACATE (UNII: 18T3X5641H) **DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)** ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) MICA (UNII: V8A1AW0880) PROPANEDIOL (UNII: 5965N8W85T) APPLE (UNII: B423VGH5S9) **GLYCERYL STEARATE CITRATE** (UNII: WH8T92A065) CAPRYLYL GLYCOL (UNII: 00YIU5438U) AMINOMETHYLPROPANOL (UNII: LU49E6626Q) **GLYCERYL MONOSTEARATE** (UNII: 2300U9XXE4) WATERMELON (UNII: 231473QB6R) **LENTIL** (UNII: 6038V6B520) FERULIC ACID (UNII: AVM951ZWST)

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:82657- 002-01	1 in 1 CARTON	03/29/2022	
l	1		45 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/29/2022		

Labeler - Cay Skin, Inc. (118574309)

Revised: 2/2022 Cay Skin, Inc.