CAY SKIN ISLE BODY OIL SPF 30- avobenzone, homosalate, octisalate, octocrylene oil 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 Body Oil SPF 30

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 10%

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.

Flammable

Do not use near heat, flame, or while smoking.

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.

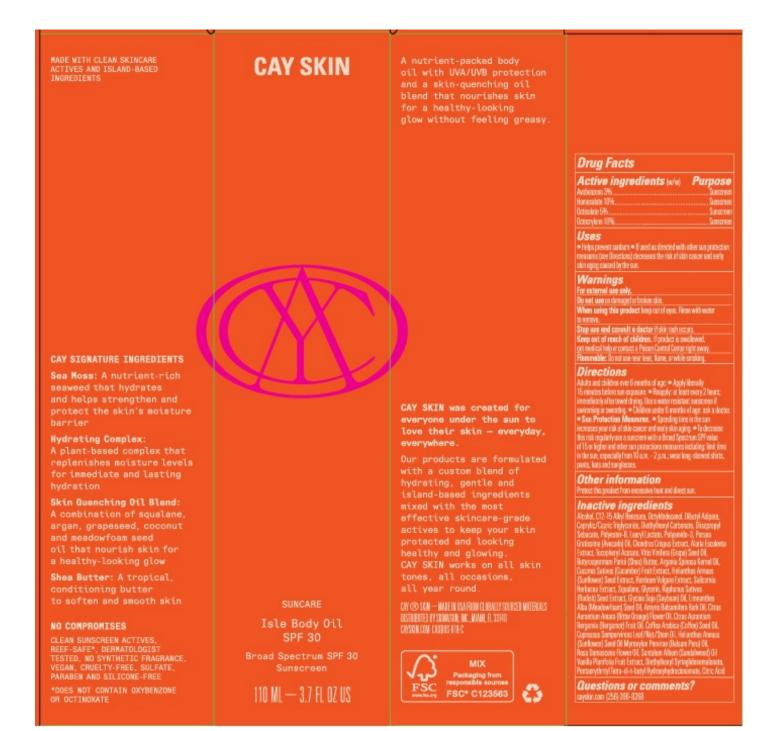
Inactive ingredients

Alcohol, C12-15 Alkyl Benzoate, Octyldodecanol, Dibutyl Adipate, Caprylic/CapricTriglyceride, Diethylhexyl Carbonate, Diisopropyl Sebacate, Polyester-8, Lauryl Lactate, Polyamide-3, Persea Gratissima (Avocado) Oil Chondrus Crispus Extract, Alaria Esculenta Extract, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Butyrospermum Parkii (Shea) Butter, Argania Spinosa Kernel Oil, Cucumis Sativus (Cucumber) Fruit Extract Heliarrthus Annuus (Sunflower) Seed Extract, Hordeum Vulgare Extract, Salicornia Herbacea Extract, Squalane, Glycerin, Raphanus Sativus (Radish) Seed Extract, Glycine Soja (Soybean) Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Amyris Balsamifera Bark Oil, Citrus Aurantium Amara (Bitter Orange) Flower Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Coffea Arabica (Coffee) Seed Oil, Cupressus Sempervirens Leaf/Nut/Stem Oil, Helianthus Annuus (Sunflower) Seed Oil, Myroxylon Pereirae (Balsam Peru) Oil, Rosa Damascena Flower Oil, Santalum Album (Sandalwood) Oil, Vanilla Planifolia Fruit Extract, Diethylhexyl Syringlidenemalonate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Citric Acid

Questions or comments?

cayskin.com (256) 396-8268

Product Packaging



CAY SKIN ISLE BODY OIL SPF 30

avobenzone, homosalate, octisalate, octocrylene oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82657-006	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				

Ingredient Name

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)

Basis of Strength

Strength

AVOBENZONE 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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

Inactive Ingredients	Chw +1
Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
ARGAN OIL (UNII: 4V59G5UW9X)	
SQUALANE (UNII: GW89575KF9)	
SOYBEAN OIL (UNII: 241ATL177A)	
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
DIETHYLHEXYL CARBONATE (UNII: YCD5000Z6L)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
VANILLA BEAN (UNII: Q74T35078H)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
CUCUMBER (UNII: YY7C30VXJT)	
SALICORNIA EUROPAEA WHOLE (UNII: 6ADL50JAKW)	
RAPHANUS SATIVUS VAR. SATIVUS SEED (UNII: A941086Q5E)	
CUPRESSUS SEMPERVIRENS WHOLE (UNII: VOIW9P606J)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
ALCOHOL (UNII: 3K9958V90M)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
AMYRIS BALSAMIFERA OIL (UNII: I1BJ961J2E)	
ARABICA COFFEE OIL (UNII: IK55HKE887)	
BALSAM PERU OIL (UNII: DIK0395679)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
SANDALWOOD OIL (UNII: X7X01WMQ5F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HORDEUM VULGARE WHOLE (UNII: 8JBE478M5Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYAMIDE-3 (12000 MW) (UNII: L7P3YWF22X)	
ALARIA ESCULENTA (UNII: EJ9JK8J58D)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82657- 006-01	1 in 1 CARTON	03/29/2022	
1		110 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part352	03/29/2022				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Cay Skin, Inc. (118574309)

Revised: 2/2022 Cay Skin, Inc.