

AUSTRALIAN GOLD SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
Prime Enterprises, 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.

Australian Gold Plant Based Lotion Sunscreen SPF 50 Face

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%

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 ask a doctor

if rash occurs

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

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 10 a.m. - 2 p.m.

wear long-sleeve shirts, pants, hats, and sunglasses

children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Water/Aqua/Eau, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Acrylic Acid/VP Crosspolymer, Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20

Other information

Protect this product from excessive heat and direct sun

May stain some fabrics or surfaces

Questions or comments?

Call 1-855-LIV-GOLD (548-4653)

Australian Gold Plant Based Lotion Sunscreen SPF 50 Face



Australian Gold

PLANT-BASED

50

LOTION SUNSCREEN

aloe & coconut

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

6 FL OZ (177 mL)

Use the natural and effective power of plants to support healthy skin. Made with Aloe Vera and Coconut Oil, this lotion is packed with nutrients your skin will love. Broad Spectrum coverage offers protection from aging UVA rays and burning UVB rays so you can be free to celebrate life outside.



This container was made with over 50% recycled materials, which creates unique imperfections.

Drug Facts	
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Uses	
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When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if rash occurs	
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Aloe Barbadensis Leaf Juice, Water/Aqua/Eau, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxethanol, Acrylic Acid/VP Crosspolymer, Fragrance (Parfum), Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20	
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*Vitamin E
*Hawaii compliant – no Oxybenzone or Octinoxate

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www.AustralianGold.com



AUSTRALIAN GOLD SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0377
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	49 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	49 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.4 mg in 1 mL
HOMOSALATE (UNII: V06SV4M9 5S) (HOMOSALATE - UNII:V06SV4M9 5S)	HOMOSALATE	98 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYISOBUTYLENE (8500 MW) (UNII: 7X53O5S2ZY)	
WATER (UNII: 059QF0K00R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Product Characteristics

Color	white (Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0377-3	88 mL in 1 TUBE; Type 0: Not a Combination Product	12/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/17/2020	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0377) , label(58443-0377) , analysis(58443-0377) , pack(58443-0377)