

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50- avobenzene, homosalate, octisalate, octocrylene, and oxybenzone 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.

Active ingredients

Avobenzene 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 2.75 %, Oxybenzone 3 %

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Cholecalciferol, Coffea Arabica Fruit Extract, Disodium EDTA, Glycerin, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Lactobacillus/Arundinaria Gigantea

Leaf Ferment Filtrate (Bamboo Isoflavones), Methylisothiazolinone, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

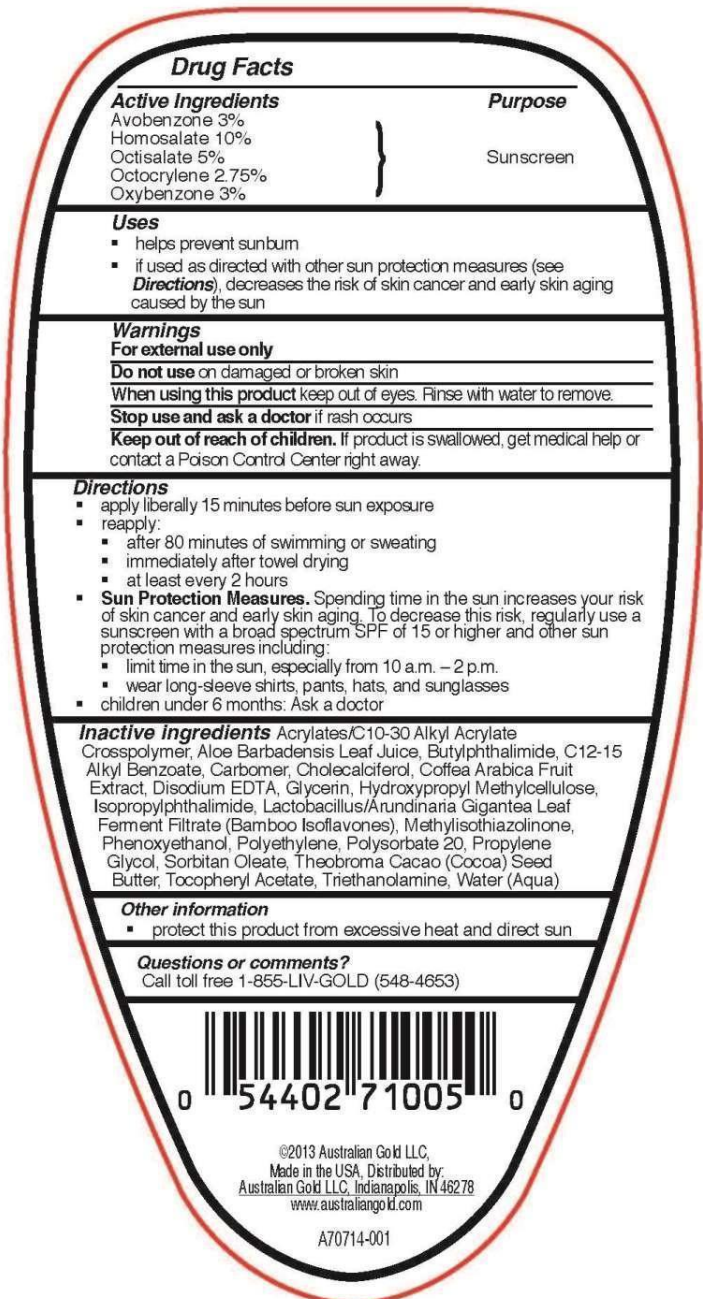
Other information

- protect this product from excessive heat and direct sun

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label



CARIBBEAN
GOLD

SUNSCREEN LOTION

BROAD

SPECTRUM

SPF 50

Infused wih antioxidant

Bamboo Isoflavones

PROTECT-HYDRATE-FIRM

- island extracts
- deeply nourishes
- vitamin enriched

PARABEN, FRAGRANCE

AND PABA-FREE

Water resistant

(80 Minutes)

8 FL OZ (237 mL)

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50			
avobenzene, homosalate, octisalate, octocrylene, and oxybenzone lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0042
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	30.5 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	76.1 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	50.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	27.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)		OXYBENZONE	20.3 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)			
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)			
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
CHOLECALCIFEROL (UNII: 1C6V77QF41)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COFFEA ARABICA FRUIT (UNII: HOX6BEK27Q)	
LACTOBACILLUS ACIDOPHILUS (UNII: 1PRR1V42V5)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0042-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/15/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0042) , pack(58443-0042) , manufacture(58443-0042) , analysis(58443-0042)