

AUSTRALIAN GOLD BROAD SPECTRUM SPF 4- avobenzone, octocrylene and oxybenzone gel

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

Avobenzone 1 %, Octocrylene 0.85 %, and Oxybenzone 0.5 %

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aing Alert:

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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. Keep away from face to avoid breathing it.

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

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands and apply to face. Use in a well-ventilated area
- reapply
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadosensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl

Methylcellulose, Isopropylphthalimide, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylisothiazolinone, Olea Europaea (Olive) Fruit Oil, Oleth 10, Phenoxyethanol, Polysilicone-15, Propylene Glycol, Sorbitan Oleate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Triethanolamine, Trimethylsiloxysilicate, Water (Aqua)

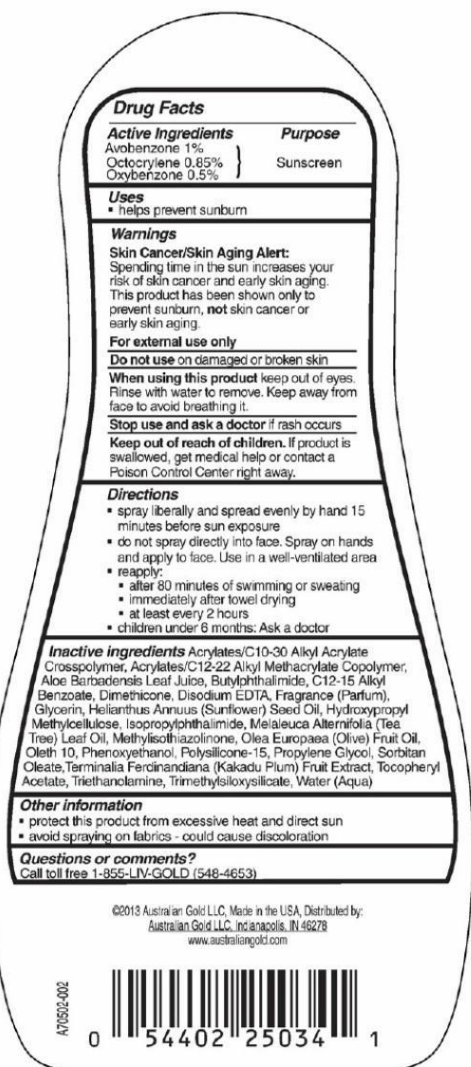
Other information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label



EXOTIC BLEND

#1 Fragrance

4

Spray Gel Sunscreen

CLEAR

BROAD SPECTRUM SPF 4

WATER RESISTANT

(80 MINUTES)

Australian

Gold

237 mL / 8 Fl. Oz

AUSTRALIAN GOLD BROAD SPECTRUM SPF 4

avobenzone, octocrylene and oxybenzone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8.3 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
OLETH-10 (UNII: JD797EF70J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9 E8 X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0076-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/21/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0076) , pack(58443-0076) , manufacture(58443-0076) , analysis(58443-0076)