

AUSTRALIAN GOLD BROAD SPECTRUM SPF 30- avobenzene, octisalate, 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

Avobenzene 3 %, Homosalate 7.5 %, Octisalate 5 %, Octocrylene 2.75 %, and Oxybenzone 2 %

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. 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 15 minutes before sun exposure
- do not spray directly into face. Use in a well-ventilated area
- 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, Acrylates/C12-22 Alkyl Methacrylate Copolymer,

Aloe Barbadensis Leaf Juice, Butylphthalimide, 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 Ferdinandaria (Kakadum 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

Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 7.5% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen

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Warnings

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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
- do not spray directly into face. Spray on hands then 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
- 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.
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EXOTIC BLEND

#1 Fragrance

X-TREME SPORT™

30
Spray Gel Sunscreen

Total Performance Formula

BROAD SPECTRUM SPF 30

WATER RESISTANT
(80 MINUTES)

Australian Gold®

8 FL. OZ. (237 mL)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.4 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	73.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26.95 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
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: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

KAKADU PLUM (UNII: 0ZQ1D2FDLI)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0150-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0150) , pack(58443-0150) , manufacture(58443-0150) , analysis(58443-0150)

Revised: 1/2020

Prime Enterprises, Inc.