

**AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 X-TREME SPORT SUNSCREEN-
avobenzone, homosalate, octisalate, octocrylene and oxybenzone spray
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 X-Treme Sport SPF 50 Spray Gel Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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

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

- 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. Do not apply in windy conditions. 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

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, Phenoxyethanol, Polysilicone-15, Propylene Glycol, Sorbitan Oleate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Triethanolamine, Trimethylsiloxysilicate, Water (Aqua)

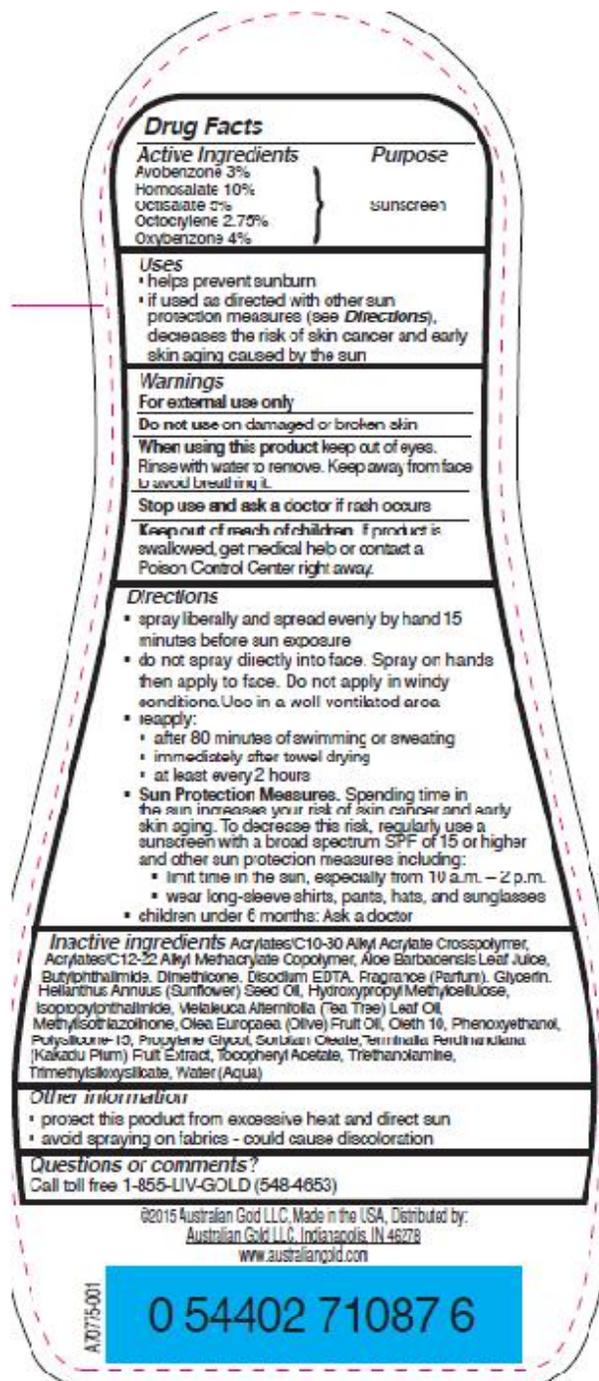
Other Information

- 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)

Australian Gold X-Treme Sport SPF 50 Spray Gel Sunscreen



Drug Facts

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Octocrylene 2.75%	
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Uses

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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

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Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Copolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Butylphenylmethane, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methacrylate, Isopropylthallimide, Metaleuca Alternifolia (Tea Tree) Leaf Oil, Methylisothiazolinone, Olea Europaea (Olive) Fruit Oil, Oleth 10, Phenoxyethanol, Polyacrylate-10, Propylene Glycol, Surfactant Oleate, Terminalia Peruviana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Triethanolamine, Trimethylsilylsilicate, Water (Aqua)

Other information

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AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 X-TREME SPORT SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0199
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	40.4 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.33 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	101.1 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.55 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0199-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	11/02/2015	
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Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0199) , manufacture(58443-0199) , label(58443-0199)

Revised: 1/2020

Prime Enterprises Inc.