

**AUSTRALIAN GOLD SPF 50 SUNSCREEN WITH INSTANT BRONZER-  
avobenzene, homosalate, octisalate, octocrylene 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.*

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**Australian Gold SPF 50 Spray Gel Sunscreen with Instant Bronzer**

***Active Ingredients***

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

***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 away from face to avoid breathing it. 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***

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin
- hold container 4 to 6 inches from the skin to apply

- do not spray directly into face. Spray on hands then apply to face
- 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***

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Caramel, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Oleth 10, Phenoxyethanol, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Styrene/Acrylates Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Trimethylsiloxysilicate, Water

### ***Other information***

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

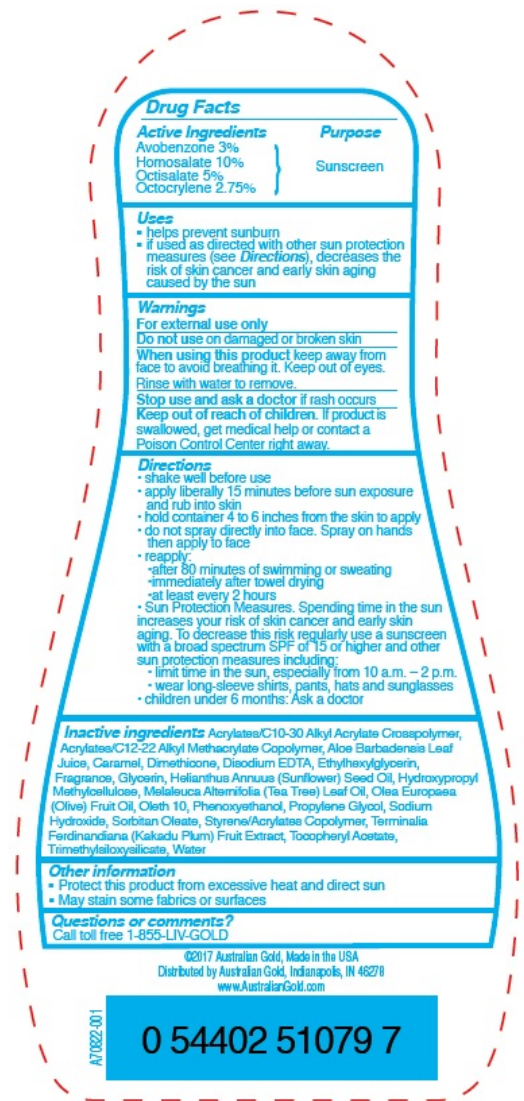
### ***Questions or comments?***

Call toll free 1-855-LIV-GOLD

**Australian Gold SPF 50 Spray Gel Sunscreen with Instant Bronzer**



4.79"



## AUSTRALIAN GOLD SPF 50 SUNSCREEN WITH INSTANT BRONZER

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0251
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.55 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.73 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.1 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>KAKADU PLUM</b> (UNII: 0ZQ1D2FDLI)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>CARAMEL</b> (UNII: T9D99G2B1R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)
<b>OLETH-10</b> (UNII: JD797EF70J)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>(C10-C30)ALKYL METHACRYLATE ESTER</b> (UNII: XH2FQZ38D8)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)

### Product Characteristics

<b>Color</b>	brown (Caramel)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0251-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2017	04/30/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/11/2017	04/30/2024

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0251) , manufacture(58443-0251) , label(58443-0251) , analysis(58443-0251)

Revised: 8/2022

Prime Enterprises Inc.