

**AUSTRALIAN GOLD SPF 30 SPORT ULTRA CHILL- octisalate, avobenzone, homosalate, 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 30 Sport Ultra Chill Spray Gel**

***Purpose***

Sunscreen

***Active Ingredients***

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

Octocrylene 5%

***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***

- 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 holds 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 value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10am-2pm
  - 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, C12-15 Alkyl Benzoate, Dimethicone, Ethylhexylglycerin, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Menthol, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Chloride, Sodium Hydroxide, Sorbitan Oleate, Tetrasodium Glutamate, Diacetate, 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 (548-4653)

## **Australian Gold SPF 30 Lotion Sport Ultra Chill Spray Gel**



Gold®

EXTREME  
SPORT

NON-GREASY  
QUICK DRY  
ANTIOXIDANT RICH

30

SPRAY GEL SUNSCREEN

WATER RESISTANT (80 MINUTES)

***ULTRA CHILL***

COOLING & REFRESHING

BROAD SPECTRUM SPF 30

8 FL OZ (237 mL)

## Australian Gold®

### SPF 30 Spray Gel Sport Ultra Chill

- Quick Dry Formula
- Phthalate Free
- Coastal Breeze Fragrance
- Antioxidant Rich
- Vegan
- Gluten Free

#### Drug Facts

<b>Active Ingredients</b>		<b>Purpose</b>
Avobenzone	3%	Sunscreen
Homosalate	7.5%	
Octisalate	5%	
Octocrylene	5%	

#### 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 Barbadosensis Leaf

Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Dimethicone, Ethylhexylglycerin, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Menthol, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Chloride, Sodium Hydroxide, Sorbitan Oleate, Tetrasodium Glutamate Diacetate, Tocopheryl Acetate, Trimethylsiloxysilicate, Water

**Other information**

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**Questions or comments?**

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[www.AustralianGold.com](http://www.AustralianGold.com)



A70875  
725049-002



**AUSTRALIAN GOLD SPF 30 SPORT ULTRA CHILL**

octisalate, avobenzene, homosalate, octocrylene spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0634
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	72.75 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.5 mg in 1 mL
<b>AVOBENZENE</b> (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	29.1 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	

<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>MENTHOL</b> (UNII: L7T10EIP3A)
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)

### Product Characteristics

<b>Color</b>	white	<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:58443-0634-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/04/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/04/2023	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
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Prime Enterprises Inc.	101946028	pack(58443-0634) , manufacture(58443-0634) , label(58443-0634) , analysis(58443-0634)
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Revised: 8/2023

Prime Enterprises Inc.