

**AUSTRALIAN GOLD INSTANT BRONZER SPF 30 SUNSCREEN- avobenzone, 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 Instant Bronzer 30 Spray Gel Sunscreen**

***Active Ingredients***

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

Octocrylene 5%

***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***

Water/Aqua/Eau, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Caramel, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Trimethylsiloxysilicate, Sodium Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Propylene Glycol, Polysorbate 20, Sorbitan Oleate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Fragrance (Parfum), Phenoxyethanol, Ethylhexylglycerin

**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 GLD INSTANT BRONZER 30 SPRAY GEL SUNSCREEN**



avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0275
<b>Route of Administration</b>	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	49 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TEA TREE OIL (UNII: VIF565UC2G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARAMEL (UNII: T9D99G2B1R)	

### 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:58443-0275-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/31/2019	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0275) , manufacture(58443-0275) , label(58443-0275) , analysis(58443-0275)

Revised: 1/2021

Prime Enterprises Inc.