

**AUSTRALIAN GOLD SPF 15 SUNSCREEN- avobenzone, 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 Ultimate Hydration 15 Spray Gel Sunscreen**

***Active Ingredients***

Avobenzone 2%

Octisalate 5%

Octocrylene 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 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, Glycerin, Butylphthalimide, 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, Disodium EDTA, Propylene Glycol, Polysorbate 20, Sorbitan Oleate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Isopropylphthalimide, Fragrance (Parfum), Phenoxyethanol, Ethylhexylglycerin

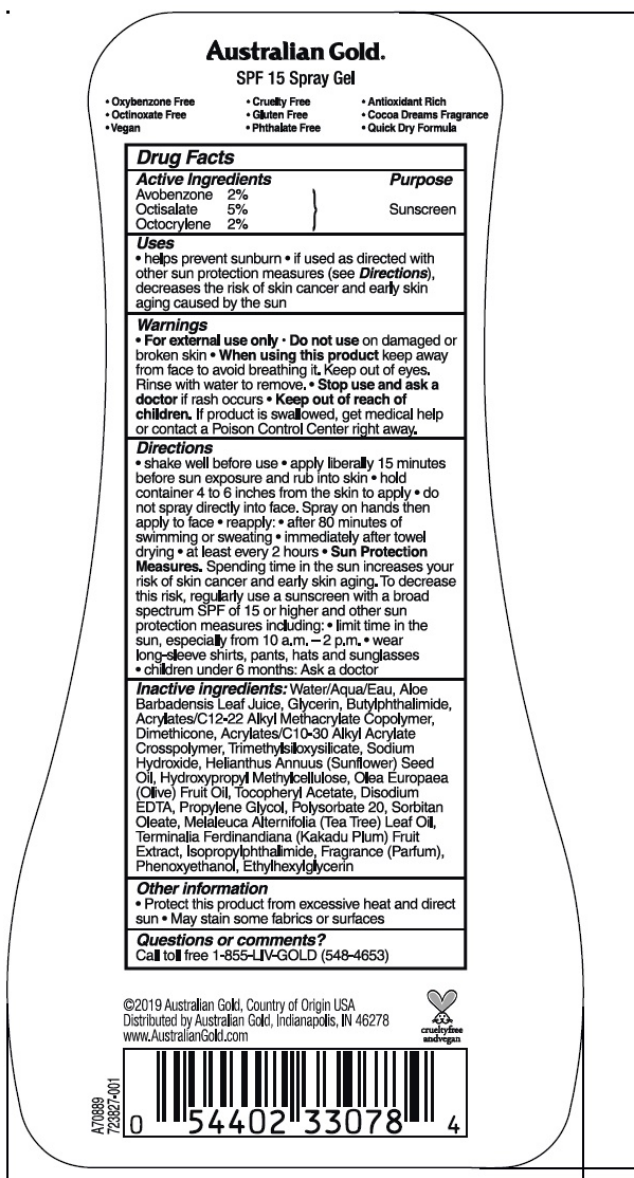
### Other information

- 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 ULTIMATE HYDRATION 15 SPRAY GEL SUNSCREEN



## AUSTRALIAN GOLD SPF 15 SUNSCREEN

avobenzone, octisalate, octocrylene spray

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:58443-0276	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE	19.6 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE	49 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)			OCTOCRYLENE	19.6 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)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
.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)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)				
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:58443-0276-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2019	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part352		10/31/2019	

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

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Prime Enterprises Inc.		101946028	pack(58443-0276) , manufacture(58443-0276) , label(58443-0276) , analysis(58443-0276)

Revised: 1/2021

Prime Enterprises Inc.