

AUSTALIAN GOLD BROAD SPECTRUM SPF 15 SUNSCREEN- octisalate, avobenzone, octocrylene lotion
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 Instant Bronzer Broad Spectrum SPF 15 Sun Screen

Active Ingredients

Avobenzone 2.0%

Octisalate 5.0%

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 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

- apply liberally 15 minutes before sun exposure and rub into skin
- 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, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, Camellia Oleifera (Green Tea) Leaf Extract, Caramel, Carbomer, Ethylhexylglycerin, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyethylene, Polysorbate 20, Sodium Hydroxide, Sorbitan Oleate, Tetrasodium Glutamate Diacetate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Sodium Chloride

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 INSTANT BRONZER Broad Spectrum SPF 15

NEW!



**Australian
Gold.**

**INSTANT
BRONZER**

NON-GREASY
CRUELTY FREE
OXYBENZONE FREE

15

LOTION SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 15

8 FL OZ (237 mL)

Australian Gold.

SPF 15 Lotion with Bronzer

- Oxybenzone Free
- Cruelty Free
- Antioxidant Rich
- Octinoxate Free
- Gluten Free
- Cocoa Dreams Fragrance
- Vegan
- Phthalate Free
- Quick Dry Formula

Drug Facts	
Active Ingredients	Purpose
Avobenzone 2%	} Sunscreen
Octisalate 5%	
Octocrylene 2%	
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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, Aloe Barbadosensis Leaf Juice, Glycerin, Butylphthalimide, Caramel, Polyethylene, Phenoxyethanol, Isopropylphthalimide, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride	
Other information	
<ul style="list-style-type: none"> • Protect this product from excessive heat and direct sun • May stain some fabrics or surfaces 	
Questions or comments?	
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www.AustralianGold.com



A72901
745010-001



octisalate, avobenzene, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZENE (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
CARAMEL (UNII: T9D99G2B1R)	
TEA TREE OIL (UNII: VIF565UC2G)	
COCOA BUTTER (UNII: 512OYT1CRR)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Product Characteristics

Color	brown (Caramel)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0603-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/17/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0603) , manufacture(58443-0603) , label(58443-0603) , analysis(58443-0603)

Revised: 1/2023

Prime Enterprises Inc.