

**AUSTRALIAN GOLD SPF 15- 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.

Australian Gold Instant Bronzer Spray Gel Sunscreen SPF 15

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

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 Spray Gel Sunscreen SPF15



Drug Facts

Active Ingredients	Purpose
Avobenzone 2%	Sunscreen
Octisalate 5%	
Octocrylene 2%	

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, 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, Isopropylphthalimide, Fragrance (Parfum), Phenoxyethanol, Ethylhexylglycerin

Other information
 • Protect this product from excessive heat and direct sun • May stain some fabrics or surfaces

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 www.AustralianGold.com



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723975-001



AUSTRALIAN GOLD SPF 15

avobenzone, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0381
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	19.4 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TEA TREE OIL (UNII: VIF565UC2G)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
CARAMEL (UNII: T9D99G2B1R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

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:58443-0381-3	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/08/2019	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part352	10/08/2019	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0381) , label(58443-0381) , analysis(58443-0381) , pack(58443-0381)

Revised: 1/2021

Prime Enterprises, Inc.