AUSTRALIAN GOLD SPF 15- avobenzone, octisalate, octocrylene spray Prime Enterprises, Inc.

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 form 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, Aloe Barbadensis leaf Juice, Glycerin, Butylphthallmide, Caramel, Phenoxyethanol, Isopropylphthalimide, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, polysorbate 20, Trimethylsiloxysilicate, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Tetrasodium Glutamte Diacetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Sodium Hydroxide, propylene Glycol, Sorbitan Oleate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride

Other information

- Protect this product form 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



BROAD SPECTRUM SPF 15

3.4 FL OZ (100mL)

Drug Facts

Active Ingredients
Avoberzone 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, Aloe Barbadensis

children under 6 months: Ask a doctor
 Inactive Ingradients: Water, Aloe Barbadensis
Leaf Juice, Glycerin, Butylphthallmide, Caramel,
Phenoxyethanol, Isopropylphthallmide, Fragrance,
Acrylates/C12-22 Alkyl Methacrylate Copolymer,
Dimethicone, Acrylates/C10-30 Alkyl Acrylate
Crosspolymer, Polysorbate 20,
Trimethylsilioxysilicate, Helianthus Annuus
(Sunflower) Seed Oil, Olea Europaea (Olive) Fruit
Oil, Tocopheryl Acetate, Tetrasodium Glutamate
Diacetate, Hydroxypropyl Methylcellulose,
Ethylhexylglycerin, Sodium Hydroxide, Propylene
Glycol, Sorbitan Oleate, Melaleuca Alternifolia (Tea
Tree) Leaf Oil, 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)

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avobenzone, octisalate, octocrylene spray

Product I	nform	ation
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Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0643
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Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20.02 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.05 g in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	20.02 g 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: 92RU3N3Y10)	
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)	
CARAMEL (UNII: T9D99G2B1R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

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:58443-0643-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/13/2022	
Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Date

Date

09/13/2022

Citation

Labeler - Prime Enterprises, Inc. (101946028)

Category

OTC Monograph Drug M020

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0643) , label(58443-0643) , analysis(58443-0643) , pack(58443-0643)

Revised: 10/2023 Prime Enterprises, Inc.