

**AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 4 SUNSCREEN-
avobenzene, and 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 Broad Spectrum SPF 4 Sunscreen

INACTIVE INGREDIENTS

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

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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. Keep away from face to avoid breathing it.

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.

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.

Purpose

Sunscreen

Uses

- helps prevent sunburn

Active Ingredients

Avobenzene 1%

Octocrylene 1%

Directions

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin
- hold container 4 to 6 inches from 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
- children under 6 months: Ask a doctor

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call Toll free 1-855-LIV-GOLD (548-4653)

Australian Gold INSTANT BRONZER SPF 4 BROAD SPECTRUM Sunscreen



AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 4 SUNSCREEN

avobenzone, and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0278
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
MELALEUCA ALTERNIFOLIA FLOWERING TOP (UNII: 5AZ4S6N66F)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CARAMEL (UNII: T9D99G2B1R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0278-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/16/2019	

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0278) , manufacture(58443-0278) , label(58443-0278) , analysis(58443-0278)

Revised: 4/2020

Prime Enterprises Inc.