

**AUSTALIAN GOLD SPF 6 SUNSCREEN LOW PROTECTION- n/a 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 Spray Oil Suncreen SPF 6 LOW PROTECTION**

**INACTIVE INGREDIENTS**

Helianthus Annuus (Sunflower) Seed Oil, Acetylated Lanolin Alcohol, Butyl Methoxydibenzoylmethane, Olea Europaea (Olive) Fruit Oil, Octocrylene, Fragrance (Parfum), Limonene, Benzophenone-3, Isopropyl Lanolate, VP/Hexadecene Copolymer, Cetyl Acetate, Tocopheryl Acetate, BHT, Daucus Carota Sativa (Carrot) Seed Oil, Diethylhexyl Syringylidenemalonate, Glycine Soja (Soybean) Oil, Coumarin, Linalool, Caprylic/Capric Triglyceride, Theobroma Cacao (Cocoa) Seed Butter, Citral, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Seed Oil, Aloe Barbadensis Leaf Extract

***Directions***

- 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 on to 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 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

***Other Information***

- Carrot Oil: Extracted from the seed of the carrot plant, this essential oil aids in moisturization for improved skin hydration
- Australian Naturals: Kakadu Plum and tea tree oil, both powerful antioxidants, help protect skin from free radicals
- Aloe Vera: Provides natural soothing and conditioning to skin
- Fragrance: take an instant vacation with the signature cocoa dreams fragrance

**Australian Gold Spray Oil Sunscreen Hydrating formula SPF 6 LOW PROTECTION**

**Australian Gold.**

**SPF 6 Spray Oil**

Walk with confidence when you intensify your color! When you rely on the nourishing care of the top sun care collection made with real, nutrient-rich ingredients, you look and feel your best for every sunny day!

- **Carrot Oil:** Extracted from the seed of the carrot plant, this essential oil aids in moisturization for improved skin hydration
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- **Fragrance:** Take an instant vacation with the signature Cocoa Dreams fragrance

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Pays d'origine États-Unis

Distributed by Australian Gold, Indianapolis, IN 46278

BIORILS/PP EU: 7170 Manage, Belgium/

RP UK London WC2H 9JQ, Great-Britain

www.AustralianGold.com



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**AUSTALIAN GOLD SPF 6 SUNSCREEN LOW PROTECTION**

n/a spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0318
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.65 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.5 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
CARROT SEED OIL (UNII: 595AO13F11)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CITRAL (UNII: T7EU0O9VPP)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
COUMARIN (UNII: A4VZ22K1WT)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LANOLIN ACID (UNII: D1CZ545P7Z)	
TEA TREE OIL (UNII: VIF565UC2G)	
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SOYBEAN OIL (UNII: 241ATL177A)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ACETATE (UNII: 4Q43814HXS)	

## Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0318-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/30/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/30/2017	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0318) , manufacture(58443-0318) , label(58443-0318) , analysis(58443-0318)

Revised: 5/2020

Prime Enterprises Inc.