

**AUSTRALIAN GOLD CARROT OIL FORMULA BROAD SPECTRUM SPF 4- avobenzene, octocrylene, oxybenzone 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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**Active ingredients**

Avobenzene 1%, Octocrylene 0.85%, and Oxybenzone 0.5%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:**

☐Spending time in the sun inceases 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.

**Directions**

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- do not spray directly into face. Spray on hands then apply to face. Use in a well-ventilated area
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor.

**Inactive Ingrediets:**

Acetylated Lanolin Alcohol, Aloe Barbadensis Extract, BHT, Caprylic/Capric Triglyceride, Cetyl Acetate, Cocos Nucifera (Coconut) Oil, Daucus Carota Sativa (Carrot) Seed Oil, Diethylhexyl Syringylidene-malonate, Fragrance (Parfum), Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Seed Oil, Isopropyl Lanolate, Macadamia Integrifolia Seed Oil, Melaleuca Alternifolia

(Tea Tree) Leaf Oil, Mineral Oil (Paraffinum Liquidum), Olea Europaea (Olive) Fruit Oil, Terminalia Ferdinandiana (Kakadu Plum) Seed Oil Extract, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, VP/Hexadecene Copolymer

**Other information**

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

**Questions or comments?**

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

**PRINCIPAL DISPLAY PANEL - 237mL Bottle Label**



**Drug Facts**

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AT16100-002

**0 54402 25020 4**

EXOTIC BLEND

#1 Fragrance

4

Spray Oil

Sunscreen

Carrot Oil Formula

Broad Spectrum SPF 4

WATER RESISTANT

(80 MINUTES)

AUSTRALIAN GOLD

237 mL / 8 Fl. Oz

## AUSTRALIAN GOLD CARROT OIL FORMULA BROAD SPECTRUM SPF 4

avobenzone, octocrylene, oxybenzone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0167
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ACETATE (UNII: 4Q43814HXS)	
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
CARROT SEED OIL (UNII: 595AO13F11)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LANOLIN (UNII: 7EV65EAW6H)	
TEA TREE OIL (UNII: VIF565UC2G)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0167-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2014	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/05/2014	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0167) , pack(58443-0167) , manufacture(58443-0167) , analysis(58443-0167)

Revised: 1/2020

Prime Enterprises, Inc.