

AUSTRALIAN GOLD SPF 30 WITH INSECT REPELLENT- octinoxate, octisalate, octocrylene, oxybenzone spray
Prime Packaging, 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 SPF 30 Bug Repellent C/S

Active Ingredients

Octinoxate 7.5%

Octisalate 5%

Octocrylene 5%

oxybenzone 4%

Purpose

Sunscreen

Uses

- helps prevent sunburn

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.

Flammable: Avoid fire, flame heat and smoking. **Contents under pressure.** Do not puncture or incinerate. Store at temperatures below 130°F.

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 help prevent sunburn, **not skin cancer or early skin aging**

Directions

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin
- 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 ingredients

Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Leaf Extract, Ethyl Butylacetylaminopropionate, Fragrance, Glycine Soja (Soybean) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, SD Alcohol 40-B, Tocopheryl Acetate

Other information

- Protect the product in this container from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or comments?

Call toll free 1-885-548-4653

AUSTRALIAN GOLD SPF 30 CONTINUOUS SPRAY SUNSCREEN with Insect Repellent



Australian Gold.

DEET FREE

SPF 30

Continuous Spray Sunscreen

WITH INSECT REPELLENT

REPELS MOSQUITOES & DEER TICKS FOR UP TO 8 HOURS

KEEP OUT OF REACH OF CHILDREN
CAUTION

See back panel for First Aid
Directions for Use and additional
Precautionary Statements.

WATER RESISTANT (80 MINUTES)

ACTIVE INGREDIENT:
3-(N-butyl-N-ethylamino)propionic acid ethyl ester* 20.00%
OTHER INGREDIENTS 80.00%
TOTAL: 100.00%
*IR3535® Insect Repellent

Net Contents: 5.6 oz (159 g)



Australian Gold.

Drug Facts	Purpose
Active Ingredients Octinoxate 7.5% Octisalate 5.0% Octocrylene 5.0% Oxybenzone 4.0%	Sunscreen

Uses
• helps prevent sunburn

Warnings
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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

Flammable: Avoid fire, flame, heat and smoking. **Contents under pressure.** Do not puncture or incinerate. Store at temperatures below 130°F.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Questions or comments?
1-855-548-4653

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 855-548-4653 or the National Pesticide Information Center at 1-800-858-7375, Monday through Friday, 8:00 AM to 12:00 PM PST, or at <http://npic.orst.edu>.

PRECAUTIONARY STATEMENTS
Hazards to Humans: **CAUTION:** For external use only. Causes moderate eye irritation. Avoid contact with eyes. Use on children under 6 months of age only with the advice of a physician.

PHYSICAL OR CHEMICAL HAZARDS: **Flammable.** Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

INSECT REPELLENT DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply liberally and evenly over dry, exposed skin. Hold container 4 to 6 inches from the skin to apply. Do not apply in windy conditions. Use in well-ventilated areas. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes and deer ticks, reapply after 8 hours, and from biting flies, reapply after 3 hours. Do not exceed 7 applications per day for adults, 3 applications per day for children. Do not apply over cuts, wounds, or irritated skin. Do not apply to excessively sunburned skin. Do not apply to children's hands. Do not allow children to handle this product.

STORAGE AND DISPOSAL
STORAGE: Store in a cool, dry area inaccessible to children.
DISPOSAL: Do not puncture or incinerate. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

02019 Australian Gold, Country of Origin USA
Manufactured for: Australian Gold, LLC
8001 Woodland Drive, Indianapolis, IN 46278

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EPA Est. No. 69804-PL-1
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DOT 2P M5655
A70623-001



AUSTRALIAN GOLD SPF 30 WITH INSECT REPELLENT

octinoxate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0162
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
SOYBEAN OIL (UNII: 241ATL177A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8 X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
TEA TREE OIL (UNII: VIF565UC2G)	
ETHYL BUTYLACETYLAMINOPROPIONATE (UNII: 65GQA237EH)	
OCTOXYNOL-7 (UNII: 8419DEW37J)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

Product Characteristics

Color	yellow (Colorless to very light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0162-4	159 g in 1 CAN; Type 0: Not a Combination Product	09/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/03/2019	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0162) , analysis(13630-0162)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0162) , pack(13630-0162)