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 swalowed, 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 sking 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 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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SOYBEAN OIL (UNII: 241ATL177A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)

Revised: 9/2020 Prime Packaging, Inc.