AUSTRALIAN GOLD BOTANICAL 70 BROAD SPECTRUM SPF 70- avobenzone, homosalate, octisalate, octocrylene 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 BOTANICAL 70 NATURAL SPRAY SUNSCREEN

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

Purpose

Sunscreen

Uses

- he **l**ps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For externa **l** use on **l**y

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 swa **ll**owed, get medica **l** help or contact a Poison Contro **l** Center right away.

F **l**ammab **l**e: Avoid fire, f **l**ame heat and smoking. **Contents under pressure.** Do not puncture or incinerate. Store at temperatures below 120°F (50°C).

Directions

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

- hold container 4 to 6 inches from the skin to apply
- do not spray directly Into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in a well-ventilated area
- 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 of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

SD Alcohol 40-B, Trimethoxybenzylidene Pentanedione, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Glycerin, Fragrance, Water, Polyester-8, Tocopheryl Acetate, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Porphyra Umbilicalis Extract, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract

Other information

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

Questions or comments?

Call toll free 1-885-LIV-GOLD (548-4653)

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avobenzone, homosalate, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0191
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	85.4 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.7 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	42.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
TRIMETHOXYBENZYLIDENE PENTANEDIONE (UNII: 322V0ACF25)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0191-4	177 mL in 1 CAN; Type 0: Not a Combination Product	10/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/04/2018	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0191) , analysis(13630-0191)

Establishment

Name	Address	ID/FEI	Business Operations

Prime Packaging, Inc.		805987059	label(13630-0191) , pack(13630-0191)