

**AUSTRALIAN GOLD MERMAID SPF 50 GLITTER SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, and 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.*

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**Mermaid SPF 50 Justice Glitter Sunscreen**

***Active Ingredients***

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

***Purpose***

Sunscreen

***Uses***

- helps 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
- shake well before use

***Warnings***

**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. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

**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:** Do not use near heat, flame or while smoking.

***Directions***

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- 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 and 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

Aloe Barbadensis Leaf Juice, Butane, Cholecalciferol, Fragrance, Mica, Propane, SD Alcohol 40-B, Titanium Dioxide, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

***Other Information***

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

**Question or comments?**

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

**Mermaid SPF 50 Glitter Sunscreen**



**Drug Facts**

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**Inactive Ingredients**  
Aloe Barbadensis Leaf Juice, Butane, Cholecalciferol, Fragrance, Mica, Pripans, SD Alcohol 40-B, Titanium Dioxide, Tocopheryl Acetate, VA/BEA/Maleate/Sebacoyl Acrylate Copolymer

**Other information**

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- avoid spraying on fabrics – could cause discoloration.

**Questions or comments?**  
Call toll free 1-855-LV-GOLD (548-4853)  
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NO CPDs  
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## AUSTRALIAN GOLD MERMAID SPF 50 GLITTER SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.04 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	86.8 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	43.4 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.87 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	34.72 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPANE (UNII: T75W9911L6)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0102-4	177 mL in 1 CAN; Type 0: Not a Combination Product	02/29/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	

**Labeler** - Prime Packaging Inc. (805987059)

**Registrant** - Prime Packaging Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0102) , analysis(13630-0102)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0102) , label(13630-0102)