

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

Mermaid SPF 50 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.

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

- apply liberally 15 minutes before sun exposure
- 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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Disodium EDTA, Ethylene/VA Copolymer, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylisothiazolinone, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polybutylene Terephthalate, Polyethylene, Polysilicone-15, Polysorbate 20, Propylene Glycol, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

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

Mermaid SPF 50 Glitter Sunscreen

Justice[™]
By AustralianGold.

Mermaid **50**
Glitter
SUNSCREEN
LOTION

*Protect & Nourish
Vitamin-Enriched
Para- & Paraben-Free
Shake Well!*

BROAD SPECTRUM SPF 50
WATER RESISTANT
(80 MINUTES)
8 FL. OZ./237mL

Drug Facts

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Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75% Oxybenzone 4%	Sunscreen

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AUSTRALIAN GOLD MERMAID SPF 50 GLITTER SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	41.04 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.78 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	102.6 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.3 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	28.22 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLENE-VINYL ACETATE COPOLYMER (50 % VINYL ACETATE) (UNII: 3H390O24S1)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TEA TREE OIL (UNII: VIF565UC2G)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DIMETHYL TEREPHTHALATE (UNII: IKZ2470UNV)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	

Product Characteristics

Color	white	Score	
Shape		Size	

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0222-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	02/08/2016		

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	analysis(58443-0222) , pack(58443-0222) , manufacture(58443-0222) , label(58443-0222)

Revised: 1/2020

Prime Enterprises Inc.