

OCEAN POTION BROAD SPECTRUM SPF 50- avobenzene, homosalate, octisalate, octocrylene lotion
Prime Enterprises

Ocean Potion SPF 50 Sunscreen Lotion

Active Ingredients

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

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

Warnings

For external use only

Do not use

on damaged or broken skin

Stop use and ask a doctor if

rash occurs

When using this product

Keep out of eyes. Rinse with water to remove

Keep out of reach of children

If 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 a Broad Spectrum SPF 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 am - 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: ask a doctor

Other Information

- for use on skin only. Avoid contact with fabric
- protect this product from excessive heat and direct sun

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Questions or comments?

oceanpotion.com

Drug Facts

Active Ingredients

Avebenzone 3.0%, Homosalate 10.0%
Octisalate 5.0%, Octocrylene 5.0%

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.

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If 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 a Broad Spectrum SPF 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor.

Other Information

- for use on skin only. Avoid contact with fabric
- protect this product from excessive heat and direct sun

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxethanol, Polyethylene Glycol, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Questions or comments?

oceanpotion.com

Distributed by
**GNL BRANDS
INTERNATIONAL LLC**
Pompano Beach, FL 33069



Made in USA
with domestic and
imported components



**OCEAN
POTION®**
SUNCARE



Scent of Sunshine™

Oxybenzone Free
No Added Parabens, Gluten
With Aloe & Vitamin E

SUNSCREEN LOTION

Broad Spectrum SPF 50
UVA/UVB Protection
Water Resistant (80 Minutes)

3.4 FL OZ (100mL)

OCEAN POTION BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0653
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
LOW DENSITY POLYETHYLENE (UNII: J245LN42AI)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0653-3	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/03/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/03/2024	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	analysis(58443-0653) , label(58443-0653) , manufacture(58443-0653) , pack(58443-0653)

Revised: 5/2024

Prime Enterprises