

PONTE VEDRA INN SPF 50 C/S SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene aerosol
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.

Aloe Up SPF 50 C/S Sunscreen Aloe Vera

Active Ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 2.75%

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

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

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 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

Aloe Barbadensis Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Mineral Oil (Paraffinum Liquidum), Polyester-8, SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other Information

- Protect this product from excessive heat and direct sun.
- Avoid spraying on fabrics - could cause discoloration.
- Store at 20°C to 25°C (68°F to 77°F)

Questions or comments?

Call toll free 1-800-950-2563

Ponte Vedra SPF 50 Continuous Spray



Ponte Vedra Inn & Club



BROAD SPECTRUM
SPF 50
SUNSCREEN
CONTINUOUS SPRAY

OXYBENZONE &
OCTINOXATE FREE

PARABEN FREE

WATER RESISTANT
(80 MINUTES)

REEF SAFE

Net Wt. 5.5 oz (156 g)



Drug Facts	
Active Ingredients	Purpose
Avobenzene 3% Homosalate 15% Octisalate 5% Octocrylene 2.75%	Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
<p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>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</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Flammable: Do not use near heat, flame or while smoking.</p>	
Directions	
<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> After 80 minutes of swimming or sweating Immediately after towel drying At least every 2 hours <p>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:</p> <ul style="list-style-type: none"> 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 	
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Other Information	
<ul style="list-style-type: none"> Protect this product from excessive heat and direct sun. Avoid spraying on fabrics - could cause discoloration. Store at 20° to 25°C (68° to 77°F) 	
Questions or Comments?	
Call toll free 1-800-950-2563	

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Manufactured for: ALOE UP 9700 W. 76th St., Ste 112, Eden Prairie, Minnesota 55344



WWW.ALOEUP.COM
1-800-950-2563

Complies with AS/NZS 2604:2012

PONTE VEDRA INN SPF 50 C/S SUNSCREEN

avobenzene, homosalate, octisalate, octocrylene aerosol

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0276
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.15 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.0275 g in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
MONOBUTYL MALEATE (UNII: F2LD7FVO1L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VINYL ACETATE (UNII: L9MK238N77)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0276-4	156 g in 1 CAN; Type 0: Not a Combination Product	08/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/04/2023	

Labeler - Prime Packaging Inc (805987059)

Registrant - Prime Packaging Inc (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0276) , analysis(13630-0276)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc		805987059	label(13630-0276) , pack(13630-0276)

Revised: 8/2023

Prime Packaging Inc