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 useon damaged or broken skin

When using this productkeep 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 $120^{\circ}F$

Stop use and ask a doctorif 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

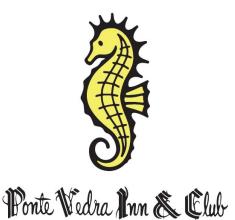
- Protect this product from excessive heat and direct sun.
- Avoid spraying on fabrics could cause discoloration.
- Store at 20°C to 25°C (68°C to 77°F)

Questions or comments?

Call toll free 1-800-950-2563

Ponte Vedra SPF 50 Continuous Spray

Complies with AS/NZS 2604:2012





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

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EMPTY BEFORE RECYCLING





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

PONTE VEDRA INN SPF 50 C/S SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene aerosol

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Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:13630-0276

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

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								
#	tem 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