PATRICKS SUNSCREEN - avobenzone, octinoxate, octocrylene, oxybenzone lotion O.P. Products, 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.

Active ingredients.....

Avobenzone 2.0%, Octinoxate 7.25%, Octocrylene 9.75%, Oxybenzone 3.0%

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- High protection against sunburn and tanning
- Retains SPF after 40 minutes of activity in the water or sweating

Warnings

- For external use only. When using this product
- Keep out of eyes
- Rinse with warm water to remove. **Stop use and ask doctor if**
- rash or irritation develops and lasts

Directions

- Apply liberally 30 minutes before sun exposure
- Children under 6 months of age consult a doctor
- Reapply as needed or after towel drying, swimming or sweating

Purpose

Purpose.....Sunscreen

• Keep out of reach of children.

Inactive ingredients

Water (Aqua), C12-15 Alkyl Benzoate, Acrylates/C12-22 Alkyl Methacrylate Copolymer (Waterproofing), Aloe Barbadensis (Aloe Vera) Leaf Juice, Isododecane, Phenoxyethanol (Preservative), Fragrance (Parfum), Tetrasodium EDTA, Carbomer, Triethanolamine, Sorbitan Oleate (Plant Derived), Tocopheryl Acetate (Vitamin E Acetate), Retinyl Palmitate (Vitamin A Palmitate), Cereus Grandiflorus (Cactus) Flower Extract, Methylisothiazolinone.

Questions or comments: 1-800-411-8801. patricks sunscreen.com

Place holder text.







delicate formula water & sweat resistant

30 SPE

UVA & UVB Protection

1 disposable wipe

www.patrickssunscreen.com

Drug Facts

Uses

- Helps prevent sunburn Higher SPF gives more sunburn protection
- High protection against sunburn and tanning
 Retains SPF after 40 minutes of activity in the water or sweating.

Warnings

- For external use only. When using this product Keep out of eyes
- Rinse with water to remove. **Stop use and ask doctor if** rash or irritation develops and lasts **Keep out of reach of children**.

Directions

Apply liberally 30 minutes before sun exposure
 Children under 6 months of age consult a doctor
 Reapply as needed or after towel drying, swimming or sweating.

Other information

• Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun • High sun protection product.

Inactive ingredients

Water (Aqua), C12-15 Alkyl Benzoate, Acrylates/C12-22 Alkyl Methacrylate Copolymer (Waterproofing), Aloe Barbadensis (Aloe Vera) Leaf Juice, Isododecane, Phenoxyethanol (Preservative), Fragrance (Parfum), Tetrasodium EDTA, Carbomer, Triethanolamine, Sorbitan Oleate (Plant Derived), Tocopheryl Acetate (Vitamin E Acetate), Retinyl Palmitate (Vitamin A Palmitate), Cereus Grandiflorus (Cactus) Flower Extract, Methylisothiazolinone.

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PATRICKS SUNSCREEN

avobenzone, octinoxate, octocrylene, oxybenzone lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:40061-990

Route of Administration TOPICAL

Active Ingredient/Active Moiety Strength **Ingredient Name Basis of Strength** Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX) Avobenzone 2 g in 100 g $7.25\;g\;\;in\;100\;g$ Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) Octinoxate Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) Octocrylene 9.75 g in 100 g Oxybenzone (UNII: 950OS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y) Oxybenzone 3 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)				
Aloe Vera Leaf (UNII: ZY81Z83H0X)				
Isododecane (UNII: A8289P68Y2)				
Phenoxyethanol (UNII: HIE492ZZ3T)				
Edetate Sodium (UNII: MP1J8420LU)				
Carbomer Copolymer Type A (UNII: 71DD5V995L)				
Trolamine (UNII: 9O3K93S3TK)				
Sorbitan Monooleate (UNII: 06XEA2VD56)				
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)				
Vitamin A Palmitate (UNII: 1D1K0N0VVC)				
Selenicereus Grandiflorus Flower (UNII: II877K4UNR)				

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40061-990-08	8 in 1 CELLO PACK		
1	NDC:40061-990-10	8.75 g in 1 PACKET		
2	NDC:40061-990-50	50 in 1 BOX		
2	NDC:40061-990-10	8.75 g in 1 PACKET		
3	NDC:40061-990-11	8.75 g in 1 PACKET		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	04/28/2011			

Labeler - O.P. Products, Inc. (840571231)

Establishment			
Name	Address	ID/FEI	Business Operations
O.P. Products, Inc.		840571231	relabel

Establishment			
Name	Address	ID/FEI	Business Operations
G.A.R. Laboratories, Inc.		074933615	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
LICO Industries, LLC		098009041	repack

Revised: 1/2012 O.P. Products, Inc.