

SUN SHIELD SUNSCREEN SPF 30- avobenzene, homosalate, octisalate, octocrylene, oxybenzone lotion

Winning Solutions

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.

Winning Solutions (as PLD) - Sun Shield Sunscreen SPF 30 (66391-3001)

Active Ingredient

AVOBENZONE 2.0%

HOMOSALATE 10.0%

OCTISALATE 5.0%

OCTOCRYLENE 5.0%

OXYBENZONE 5.0%

Purpose

SUNSCREEN

Uses

- HELPS PREVENT SUNBURN

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 or irritation develops and lasts.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control center right away.

Directions

- apply generously 15 minutes before sun exposure.

Reapply:

- after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
 - under 6 months of age: ask a doctor
- 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 value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m.-2 p.m. and wear long-sleeved shirts, pants, hats and sunglasses. For use on skin only.

Inactive ingredients

water, glycerin, stearic acid, cetyl alcohol, aloe barbadensis leaf, c12-15 alkyl benzoate, dea-cetyl phosphate, vp/eicosene copolymer, phenoxyethanol, dimethicone, triethanolamine, carbomer, titanium dioxide, glycereth-2 cocoate, tocopheryl acetate, retinyl palmitate, iodopropynyl butylcarbamate, chamomilla recutitita (matricaria) flower extract

Miracle of Aloe

SUN SHIELDTM SUNSCREEN

SPF 30

- 40% Pure Aloe Gel
- Water Resistant
- Broad Spectrum UVA and UVB Protection

1 fl oz (30 mL)

Drug Facts

Active ingredients	Purpose
Avobenzone 2.0%	Sunscreen
Homosalate 10.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 5.0%	Sunscreen
Oxybenzone 5.0%	Sunscreen

Uses ■ helps prevent sunburn

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 or irritation develops and lasts. Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control center right away.

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Inactive ingredients water, glycerin, stearic acid, cetyl alcohol, aloe barbadensis leaf, c12-15 alkyl benzoate, dea-cetyl phosphate, vp/eicosene copolymer, phenoxyethanol, dimethicone, triethanolamine, carbomer, titanium dioxide, glycereth-2 cocoate, tocopheryl acetate, retinyl palmitate, iodopropynyl butylcarbamate, chamomilla recutitita (matricaria) flower extract

CERTIFIED Ultra Aloe

This product contains 40% pure Ultra Aloe gel (aloe barbadensis leaf juice) by volume.

Distributed by MIRACLE OF ALOE®
 P.O.B. 612688, Dallas, TX 75261-2688
 Product #18051. Questions or comments call
 toll-free 1-800-966-2563 Made in U.S.A.
www.miracleofaloe.com

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SUN SHIELD SUNSCREEN SPF 30

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66391-3001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66391-3001-1	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/26/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/26/2023	

Labeler - Winning Solutions (962718300)

Revised: 1/2023

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