

SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion

Amazon

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 3%

Homosalate 10%

Octisalate 5%

Octocrylene 6%

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

Stop use and ask a doctor if

- rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control right away.

Directions

- apply liberally 15 minutes before sun exposure
- apply to all skin exposed to the sun
- 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 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.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

inactive ingredients

water, silica, dimethicone, potassium cetyl phosphate, benzyl alcohol, beeswax, glyceryl stearate, PEG-100 stearate, caprylyl methicone, cetyl dimethicone, dimethicone/PEG-10/15 crosspolymer, sodium polyacrylate, behenyl alcohol, xanthan gum, glycerin, pentylene glycol, acrylates/C12-22 alkyl methacrylate copolymer, ethylhexyl stearate, chlorphenesin, disodium EDTA, fragrance, diethylhexyl 2,6-naphthalate, BHT, trideceth-6

Adverse reactions section

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914.000/914AA

principal display panel

SOLIMO

Sheer Facial

Sunscreen

Lotion

BROAD SPECTRUM SPF 30

Water resistant (80 minutes)

Light, clean feel

Dermatologist tested

Oxybenzone &

Octinoxate free

3 FL OZ (88 mL)



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Sheer Facial Sunscreen Lotion

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SUNSCREEN			
avobenzone, homosalate, octisalate, octocrylene lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-914
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	90 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	1000 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	250 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	360 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
DIMETHICONE PEG-10 PHOSPHATE (UNII: O7Q5NJ7X88)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DOCOSANOL (UNII: 9G1OE216XY)	
xanthan gum (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ALLYL METHACRYLATE (UNII: G2IG50653Z)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
diethylhexyl 2,6-naphthalate (UNII: I0DQJ7YGXM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-914-21	89 mL in 1 TUBE; Type 0: Not a Combination Product	09/08/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	09/08/2019	
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Labeler - Amazon (128990418)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(72288-914)

Revised: 4/2020

Amazon