DAILY MOISTURIZER- octinoxate, octisalate lotion Amazon.com Services LLC

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.

Solimo 338.002 338AC

active information

Avobenzone 3%

Octinoxate 7.5%

Octisalate 2%

Purpose

Sunscreen

Use

- 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 the 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 Center right away.

Directions

- apply liberally 15 minures before sun exposure
- reapply at least every 2 hours:
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of 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 the time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeved shirts, pants hats and sunglasses
- children umder 6 months of age: ask a doctor

Other information

protect the product from excessive heat and direct sun

Inactive ingredients

water, C12-15 alkyl benzoate, cetearyl alcohol, glycerin, dimethicone, Glycine soja (soybean) seed extract, bis-phenylpropyl dimethicone, arachidyl alcohol, cetearyl glucoside, benzyl alcohol, panthenol, ethylene/acrylic acid copolymer, behenyl alcohol, steareth-2, fragrance, steareth-21, polymethyl methacrylate, polyacrylamide, arachidyl glucoside, disodium EDTA, C13-14 isoparaffin, laureth-7, silica, chlorphenesin, BHT, titanium dioxide, mica

Adverse Reactions Section

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principal display panel

Solimo

Absolutely

Beaming Daily

Moisturizer

SUNSCREEN

BROAD SPECTRUM SPF 15

4 FL OZ (118 mL)



DAILY MOISTURIZER

octinoxate, octisalate lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-338	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) **GLYCERIN** (UNII: PDC6A3C0OX) **DIMETHICONE** (UNII: 92RU3N3Y10) **SOYBEAN** (UNII: L7HT8F1ZOD) BIS-PHENYLPROPYL DIMETHICONE (15 CST) (UNII: 4836494CFT) ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU) CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) BENZYL ALCOHOL (UNII: LKG8494WBH) PANTHENOL (UNII: WW9CM0067Z) ACRYLIC ACID/ETHYLENE COPOLYMER (600 MPA.S) (UNII: 1PEZ3NLY6I) DOCOSANOL (UNII: 9G10E216XY) STEARETH-2 (UNII: V56DFE46J5) **STEARETH-21** (UNII: 53J3F32P58) POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4|11) ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ) **EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)** C13-14 ISOPARAFFIN (UNII: E4F12ROE70) **LAURETH-7** (UNII: Z95S6G8201) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) CHLORPHENESIN (UNII: 1670DAL4SZ) **BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K) **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) MICA (UNII: V8A1AW0880)

Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288- 338-26	1 in 1 CARTON	04/26/2018	
1		188 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/26/2018	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-338)
Vi-Jon, LLC		790752542	manufacture(72288-338)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72288-338)

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