### COMPLETE BEAUTY- octinoxate, zinc oxide lotion Amazon.com Services LLC

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# Complete Beauty Lotion SPF-15 - Sensitive Skin 503.002 503AB

#### **Claims**

**SOLIMO** 

**Beauty Lotion** 

**BROAD SPECTRUM SPF 15** 

**SUNSCREEN** 

**MOISTURIZER** 

**SPF 15** 

### **Active ingredient**

Octinoxate 6.0%

Zinc oxide 3.0%

### **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 Center right away.

#### **Directions**

- apply liberally 15 minutes 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 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 from excessive heat and direct sun

### **Inactive ingredients**

water, glycerin, isohexadecane, sodium acrylate/sodium acryloyldimethyl taurate copolymer, polysorbate 80, laureth-7, PEG/PPG-20/20 dimethicone, steareth-21, stearyl alcohol, Gossypium herbaceum (cotton) seed oil, behenyl alcohol, tocopheryl acetate, cetyl alcohol, steareth-2, disodium EDTA, Aloe barbadensis leaf extract, oleth-3 phosphate, benzyl alcohol, chlorphenesin

### side panel claims

Beauty Lotion
BROAD SPECTRUM SPF 15
SUNSCREEN
MOISTURIZER
SPF 15

#### **Adverse Reactions**

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503.002/503AB

### principal display panel

**SOLIMO** 

**Beauty Lotion** 

**BROAD SPECTRUM SPF 15** 

**SUNSCREEN** 

Sensitive skin

6 FL OZ (177 mL)



### octinoxate, zinc oxide lotion

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72288-503

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
LAURETH-7 (UNII: Z95S6G8201)	
PEG/PPG-20/20 DIMETHICONE (UNII: BA94B7CK8K)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
COTTONSEED OIL (UNII: H3E878020N)	
DOCOSANOL (UNII: 9G10E216XY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARETH-2 (UNII: V56DFE46J5)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:72288- 503-30	1 in 1 CARTON	04/25/2018	
	1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part352	04/25/2018	

## **Labeler -** Amazon.com Services LLC (128990418)

# **Registrant -** Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-503)

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