

SHIMMERY SUN- octinoxate titanium dioxide lotion
CA-BOTANA INTERNATIONAL

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.

Sunscreen Shimmery Sun

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 product is swallowed, get medical help or contact a poison control center right away.

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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 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-sleeve shirts, pants, hats, and sunglasses. Protect this product from excessive heat and direct sun

ALANINE, ALOE VERA LEAF, ARGININE, ASCORBIC ACID, ASCORBYL PALMITATE, .ALPHA.-BISABOLOL, (+/-)-,CAPRYLIC/CAPRIC MONO/DIGLYCERIDES, CETEARYL ISONONANOATE, CETYL ALCOHOL, CITRIC ACID MONOHYDRATE, COCONUT, ETHYLHEXYLGLYCERIN, GLYCERIN, GLYCERYL MONOSTEARATE, GLYCINE, SUNFLOWER OIL, MICA, NIACIN, OLEA EUROPAEA LEAF, PANTHENOL, PHENOXYETHANOL, LECITHIN, SOYBEAN, POTASSIUM SORBATE, SODIUM PYROPHOSPHATE, PENTYLENE GLYCOL, PROPANEDIOL, ALMOND OIL, ROSA MOSCHATA OIL, ROSEMARY, HYALURONATE SODIUM, SODIUM CITRATE, SORBITAN, TOCOPHEROL, UREA, GRAPE SEED OIL, XANTHAN GUM, WATER

Sunscreen

For external use only.

Avoid contact with eyes.

Keep out of reach of children.


Do not apply to open wounds.

STOP USE AND ask a doctor if condition worsens or symptoms persist for more than seven days, discontinue use of the product.

Front

Back

**daily defense
facial sunscreen
with aloe & grape seed**



LATHER
broad spectrum
SPF 30

2 fl oz / 59 ml

aloe · moisturizing · grape seed · antioxidant

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 5%	Sunscreen
Octinoxate 4%	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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours • children under 6 months: 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 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-sleeve shirts, pants, hats, and sunglasses

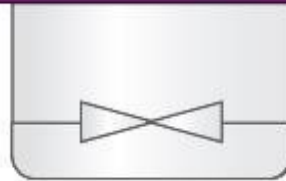
Inactive ingredients: *Alanine, Aloe Barbadiana Leaf Extract, Arginine, Ascorbic Acid, Ascorbyl Palmitate, Bisabolol, Caprylic/Capric triglyceride, Cetearyl Isononanoate, Cetyl Alcohol, Citric Acid, Coco Caprylate, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Glycerin, Glyceryl Stearate SE, Glycine, Helianthus Annuus (Sunflower) Seed Oil, Mica, Niacin, Olea Europaea (Olive) Leaf Extract, Panthenol, Phenylethanol, Phospholipids, Potassium Sorbate, Proline, Perylene Glycol, Propanediol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosa Canina (Rosehip) Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hyaluronate, Sodium Citrate, Sorbitan Monostearate, Tetrasodium EDTA, Tocopherol, Vitis Vinifera (Grape) Seed Extract, Water (Aqua), Xanthan Gum.*

Other information • Protect this product from excessive heat and direct sun

NDC 36783-0022-01 Distributed by LATHER, Inc. Pleasanton, CA 94566 net 6234
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packaging made with EcoPure® #1



Ø35mm H: 100 mm
C:108mm

Art Release Date	Revision #	Rev Description	Formula
10/16/2013	R1	Updated all per FDA regulations / Updated formula	6234

Screen Area: W 4.252 x H 3.937 in

Titanium Dioxide, Octinoxate

SHIMMERY SUN

octinoxate titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 113.4 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.5 g in 113.4 g

Inactive Ingredients

Ingredient Name	Strength
ALANINE (UNII: OF5P57N2ZX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGININE (UNII: 94ZLA3W45F)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT (UNII: 3RT3536DHY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCINE (UNII: TE7660XO1C)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MICA (UNII: V8A1AW0880)	
NIACIN (UNII: 2679MF687A)	
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ROSA MOSCHATA OIL (UNII: J99W255AWF)	
ROSEMARY (UNII: IJ67X351P9)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITAN (UNII: 6O92ICV9RU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-014-02	50 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/10/2013	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-014)

Revised: 10/2013

CA-BOTANA INTERNATIONAL