

SUN ESSENTIAL - 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.

6234 Sunscreen Sun Essential

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.



Drug Facts

Active Ingredients

Titanium Dioxide 4% Sunscreen
 Octinoxate 5% Sunscreen

Purpose

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 Barbadensis Leaf Extract, Arginine, Ascorbic Acid, Ascorbyl Palmitate, Bisabolol, Caprylic/Capric Triglyceride, Cetearyl Isononanoate, Cetyl Alcohol, Citric Acid, Coco Caprylate, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Glycerine, Glyceryl Stearate SE, Glycine, Helianthus Annuus (Sunflower) Seed Oil, Mica, Niacin, Olea Europaea (Olive) Leaf Extract, Panthenol, Phenoxyethanol, Phospholipids, Potassium Sorbate, Proline, Tetrasodium EDTA, Pentylene Glycol, Propanediol (Zermea), Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosa Canina (Rosehip) Oil, Rosmarinus Officinalis Leaf (Rosemary) Extract CO2, Sodium Hyaluronate, Sodium Citrate, Sorbitan Monostearate, Tocopherol, Urea, Vitis Vinifera (Grape) Seed Extract, Xanthan Gum, Water (Aqua)

Other information • protect this product from excessive heat and direct sun.

NDC 35192-009-06 Code: 6234

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Titanium Dioxide, Octinoxate

SUN ESSENTIAL

octinoxate titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	17.75 g in 355 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	14.2 g in 355 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)	
UREA (UNII: 8W8T17847W)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-009-06	355 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2012	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture

Revised: 6/2012

CA-BOTANA INTERNATIONAL