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

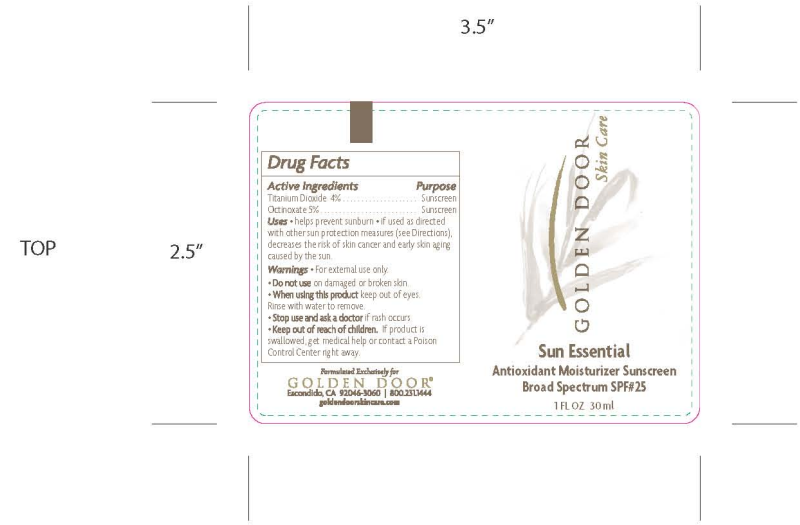
For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.

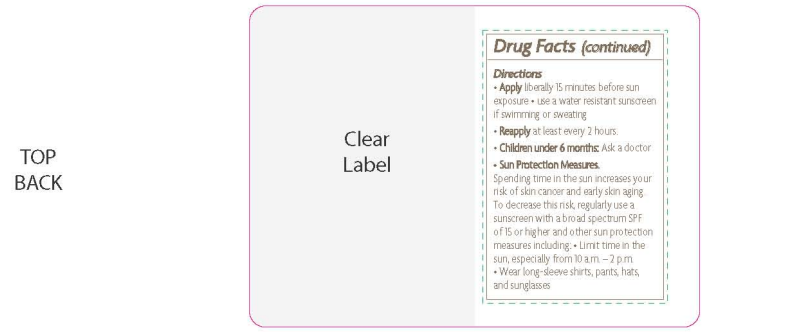
Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply: at least 2 hours. Children under 6 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

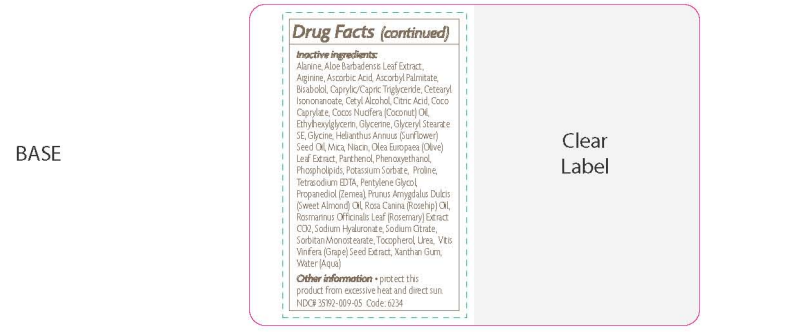
ALANINE, ALOE VERA LEAF, ARGININE, ASCORBIC ACID, ASCORBYL PALMITATE, .ALPHA.-BISABOLOL, (+/-)-,CAPRYLIC/CAPRIC MONO/DIGLYCERIDES, CETEARYL ISONONANOATE, CETYL ALCOHOL, CITRIC ACID MONOHYDRATE, COCONUT, ETHYLHEXYLGLYCERIN, GLYCERIN, GLYCERYL MONOSTEARATE, GLYCINE, SUNFLOWER OIL, MICA, NIACIN, OLEA EUROPAEA 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.







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	1.5 g in 30 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.20 g in 30 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: MJ95C3OH47)	
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: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-009-05	30 g in 1 TUBE		

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