SUN DEFENSE CREAM- 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.

Warning and Precautions Section

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.

DOSAGE & ADMINISTRATION SECTION

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

INACTIVE INGREDIENT SECTION

ALOE VERA LEAF

ALUMINUM STARCH OCTENYLSUCCINATE

ASCORBIC ACID

ASCORBYL PALMITATE

BORON NITRIDE

CAMELLIA SINENSIS FLOWER

CAPRYLIC/CAPRIC MONO/DIGLYCERIDES

STEARYL ALCOHOL

CETYL ALCOHOL

CETEARYL ESONONANOATE

CITRIC ACID MONOHYDRATE

CITRUS AURANTIUM FLOWER OIL

COCO-CAPRYLATE

ETHYLHEXYLGLYCERIN

GLYCERIN

SUNFLOWER OIL

NEACEN

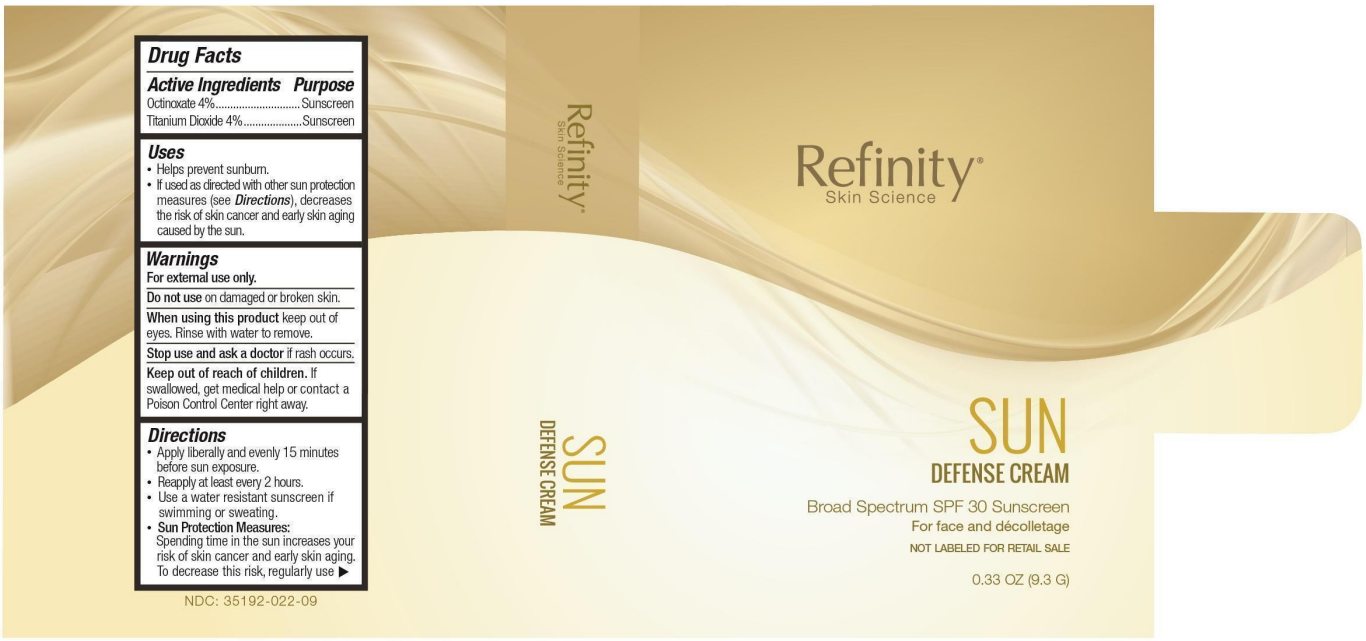
PANTHENOL

PHENOXYETHANOL
EGG PHOSPHOLIPIDS
POTASSIUM SORBATE
PROPANEDIOL
ROSMARINUS OFFICINALIS FLOWERING TOP OIL
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER
SORBITAN STEARATE
TOCOPHEROL
GRAPE SEED OIL
XANTHAN GUM
WATER

OTC - ACTIVE INGREDIENT SECTION
OCTINOXATE
TITANIUM DIOXIDE

OTC - PURPOSE SECTION

keep out of reach of children section
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.



SUN DEFENSE CREAM

octinoxate titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35192-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.372 g in 0.375 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.372 g in 0.375 g

Inactive Ingredients	
Ingredient Name	**Strength**
HYALURONIC ACID (UNII: S270N0TRQY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
CAMELLIA SINENSIS FLOWER (UNII: 912BJY2J17)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

COCO-CAPRYLATE (UNII: 4828G836N6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACIN (UNII: 2679MF687A)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPANEDIOL (UNII: 5965N8W85T)	
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
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:35192-022-09	9.3 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/01/2015	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-022)

Revised: 9/2015 CA-BOTANA INTERNATIONAL