#### UMBRELLA- octinoxate titanium dioxide lotion CA-BOTANA INTERNATIONAL

-----

#### Umbrella Sunscreen

#### 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

#### **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.

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



Product Information					
Product Type	HUMAN OTC DRUG	Item Code	e (Source) NDC:351		92-007
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingree	dient Name		Basis of Streng	th S	trength
OCTINOXATE (UNII: 4Y5P7MUD51		7MUD51)	OCTINOXATE		8 g in 56.7 g
TITANIUM DIOXIDE (UNII: 15FIX9)			TITANIUM DIOXIDE		8 g in 56.7 g
Inactive Ingredients					
	Ingredient Nar	ne			Strength
ALOE VERA LEAF (UNII: ZY81Z83	H0X)				
ALUMINUM STARCH OCTENYLS	UCCINATE (UNII: 19PJ0062	94)			
ASCORBIC ACID (UNII: PQ6CK8PD	00R)				
ASCORBYL PALMITATE (UNII: QN	83US2B0N)				
BORON NITRIDE (UNII: 2U4T60A6	YD)				
CAMELLIA SINENSIS FLOWER (U	JNII: 912BJY2J17)				
CAPRYLIC/CAPRIC MONO/DIGLY	CERIDES (UNII: U72Q2I8C	85)			
STEARYL ALCOHOL (UNII: 2KR89)	4H1Y)				
CETYL ALCOHOL (UNII: 936JST6JO	CN)				
CETEARYL ISONONANOATE (UN	II: P5001U99NI)				
CITRIC ACID MONOHYDRATE (U	NII: 2968PHW8QP)				
CITRUS AURANTIUM FLOWER O	IL (UNII: D4BGE91OXH)				
COCO-CAPRYLATE (UNII: 4828G8	336N6)				
ETHYLHEXYLGLYCERIN (UNII: 14	7D247K3P)				
GLYCERIN (UNII: PDC6A3C0OX)					
SUNFLOWER OIL (UNII: 3W1JG795	5YI)				
NIACIN (UNII: 2679MF687A)					
PANTHENOL (UNII: WV9CM0067Z)					
PHENOXYETHANOL (UNII: HIE492	ZZ3T)				
EGG PHOSPHOLIPIDS (UNII: 1Z74	4184RGV)				
POTASSIUM SORBATE (UNII: 1VP	U26JZZ4)				
PROPANEDIOL (UNII: 5965N8W85	Γ)				
ROSMARINUS OFFICINALIS FLO	WERING TOP OIL (UNII: (	DXN0D3N28L)			
PEG-9 DIGLYCIDYL ETHER/SODI	UM HYALURONATE CRO	SSPOLYMER (U	NII: 788QAG3W8A)		
SORBITAN MONOSTEARATE (UN	III: NVZ4I0H58X)				
TOCOPHEROL (UNII: R0ZB2556P8	3)				
GRAPE SEED OIL (UNII: 930MLC8)	KGG)				
XANTHAN GUM (UNII: TTV12P4NE	E)				

# Item Code	Package Description	Marketing Start Date	Marketing End Date
	56.7 g in 1 TUBE; Type 0: Not a Combination 0 Product	08/01/2013	
Marketing I	nformation		
Marketing I Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing	Application Number or Monograph	-	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

# Registrant - RODOLFO UGELSTAD (106276728)

## **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-007)

Revised: 10/2023

#### CA-BOTANA INTERNATIONAL