# UMBRELLA- octinoxate titanium dioxide lotion CA-BOTANA INTERNATIONAL

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### **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** 

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.

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



### octinoxate titanium dioxide lotion

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35192-007

**Route of Administration** TOPICAL

| Active Ingredient/Active Moiety  |                          |                   |  |  |  |
|--|--------------------------|-------------------|--|--|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength          |  |  |  |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE               | 2.268 g in 56.7 g |  |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2IP) (TITANIUM DIOXIDE - UNII:15FIX9V2IP) | TITANIUM DIOXIDE         | 2.268 a in 56.7 a |  |  |  |

| Inactive Ingredients  |          |
|---|----------|
| Ingredient Name   | Strength |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)   |          |
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)                       |          |
| ASCORBIC ACID (UNII: PQ6CK8PD0R)  |          |
| ASCORBYL PALMITATE (UNII: QN83US2B0N)                                     |          |
| BORON NITRIDE (UNII: 2U4T60A6YD)  |          |
| CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)                               |          |
| CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)                      |          |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y)  |          |
| CETYL ALCOHOL (UNII: 936JST6JCN)  |          |
| CETEARYL ISONONANOATE (UNII: P5001U99NI)                                  |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)                                |          |
| CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)                            |          |
| COCO-CAPRYLATE (UNII: 4828G836N6)   |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                                     |          |
| GLYCERIN (UNII: PDC6A3C0OX)   |          |
| SUNFLOWER OIL (UNII: 3W1JG795YI)  |          |
| NIACIN (UNII: 2679MF687A)   |          |
| PANTHENOL (UNII: W/9CM0067Z)  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)   |          |
| EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)                                      |          |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4)                                      |          |
| PROPANEDIOL (UNII: 5965N8W85T)  |          |
| ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)               |          |
| PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A) |          |
| SORBITAN MONOSTEARATE (UNII: NVZ 4I0H58X)                                 |          |
| TOCOPHEROL (UNII: R0ZB2556P8)   |          |
| GRAPE SEED OIL (UNII: 930MLC8XGG)   |          |
| XANTHAN GUM (UNII: TTV12P4NEE)  |          |
| WATER (UNII: 059QF0KO0R)  |          |

### **Packaging**

| #                     | Item Code  | Package Description                         | Marketing Start<br>Date | Marketing End<br>Date |  |
|-----------------------|--|---|-------------------------|-----------------------|--|
| 1                     | NDC:35192-007- 56.7 g in 1 TUBE; Type 0: Not a Combination 01 08/01/2013 |   |                         |                       |  |
|                       |  |   |                         |                       |  |
| Marketing Information |  |   |                         |                       |  |
|                       | Marketing<br>Category  | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| 01                    | C Monograph Dru  | g M020                                      | 08/01/2013              |                       |  |
|                       |  |   |                         |                       |  |

## 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)     |  |  |  |  |

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