ULTRA UMBRELLA- octinoxate titanium dioxide lotion
CA-BOTANA INTERNATIONAL

Ultra Umbrella 4552-815

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

COCO-CAPRYLATE

ETHYLHEXYLGLYCERIN

GLYCERIN

SUNFLOWER OIL

NEACEN

LAMINARIA DIGITATA

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

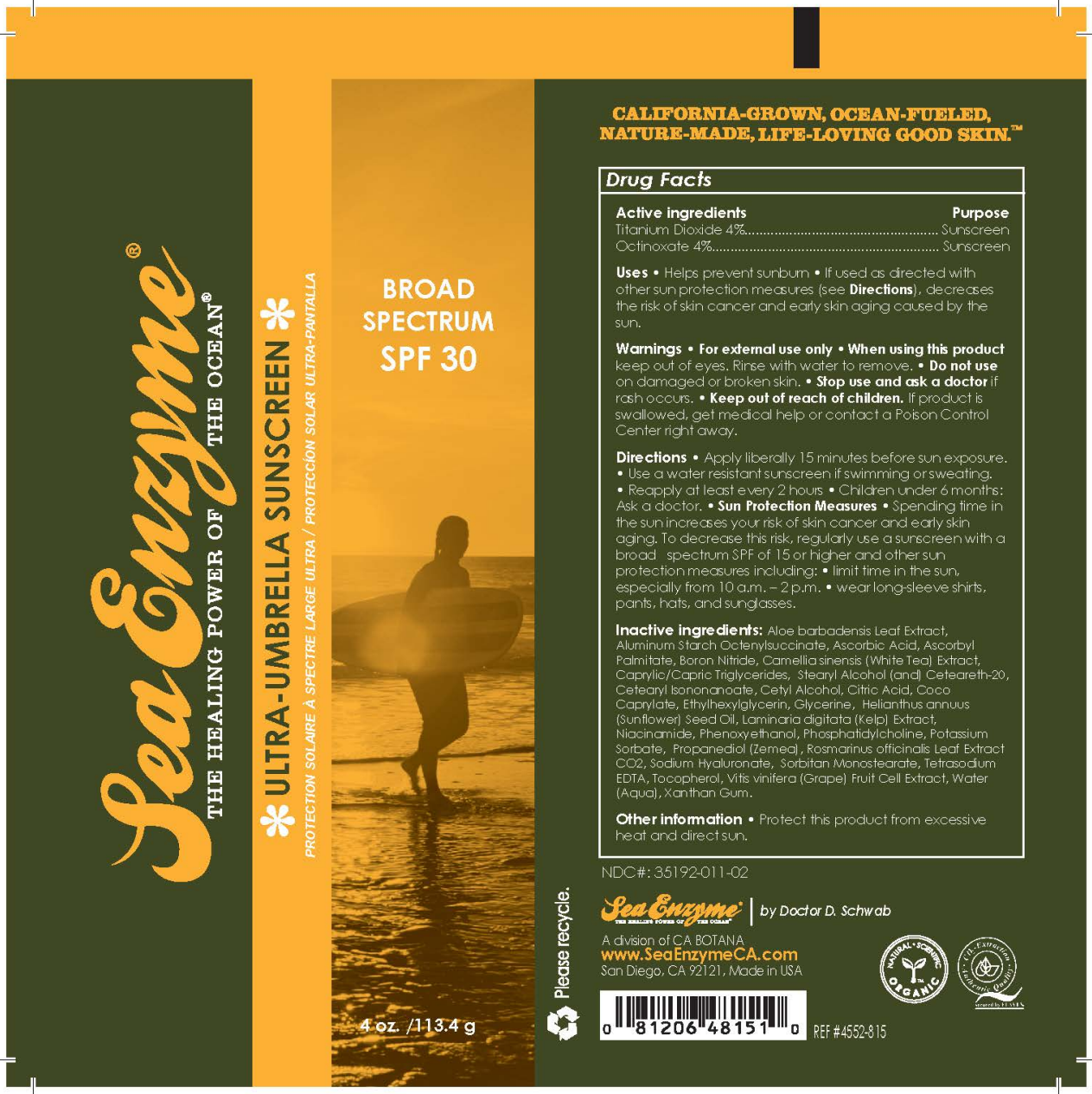
symptoms persist for more than seven days, discontinue

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



ULTRA UMBRELLA

octinoxate titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35192-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.536 g in 113.4 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.536 g in 113.4 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
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: P5O01U99NI)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
NIACIN (UNII: 2679MF687A)	
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: NVZ4I0H58X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-011-02	113.4 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/01/2013	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-011)

Revised: 7/2025 CA-BOTANA INTERNATIONAL