

UMBRELLA SUNSCREEN- 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.

6236 Umbrella Sunscreen Lotion

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

ALOE VERA LEAF, ALUMINUM STARCH OCTENYLSUCCINATE, ASCORBIC ACID, ASCORBYL PALMITATE, BORON NITRIDE, CETOSTEARYL ALCOHOL, CETEARYL ISONONANOATE, CITRIC ACID MONOHYDRATE, CAPRYLIC/CAPRIC MONO/DIGLYCERIDES, ETHYLHEXYLGLYCERIN, GLYCERIN, SUNFLOWER OIL, ISOMALT, LECITHIN SOYBEAN, MACADAMIA OIL, NIACIN, PANTHENOL, PHENOXYETHANOL, LECITHIN SOYBEAN, POTASSIUM SORBATE, PROPANEDIOL, ROSA MOSCHATA OIL, ROSEMARY, SODIUM BENZOATE, HYALURONATE SODIUM, TETRASODIUM IMINODISUCCINATE, TOCOPHEROL, GRAPE SEED OIL, WATER

Sunscreen

Titanium Dioxide, Octinoxate

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.

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



SUPREME FACE SHIELD

Moisturizing Protection

Broad Spectrum
Sunscreen
SPF 40

2oz (56.7g)

DRUG FACTS	
ACTIVE INGREDIENTS	PURPOSE
Octinoxate 7.5%	Sunscreen
Titanium Dioxide 6%	Sunscreen
USES • Helps prevent sunburn. WARNINGS • 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.	
DIRECTIONS • Apply liberally 15 minutes before sun exposure. • Use a water resistant sunscreen if swimming or sweating. • Reapply at least every 2 hours. • Children under 6 months: Ask a doctor. • Optional: apply to all skin exposed to the sun.	
ADDITIONAL DIRECTIONS • Sun protection measures. 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.	
INACTIVE INGREDIENTS Aloe barbadensis leaf extract, Aluminum starch octenylsuccinate, Ascorbic acid, Ascorbyl palmitate, Boron nitrate, Camellia sinensis (white tea) extract, Caprylic/Capric triglyceride, Cetearyl isononanoate, Cetyl alcohol, Citric acid, Citrus sinensis (orange) oil, Coco caprylate, Emulsifying wax, Ethylhexylglycerin, Glycerine, Isomalt, Lecithin, Macadamia ternifolia seed (macadamia) oil, Niacin, Panthenol, Phenylethanol, Phospholipids, Potassium sorbate, Propanediol (sorbitol), Rosa canina fruit (rosehip) oil, Rosmarinus officinalis leaf (rosemary) extract CO ₂ , Sodium benzoate, Sodium hyaluronate, Tetrasodium EDTA, Tocopherol, Vitis vinifera (grape) seed extract, Water (aqua), Xanthan gum.	
OTHER INFORMATION • Protect this product from excessive heat and direct sun.	
Questions or Comments? Call us at (310) 855-1150	
Ref. #6236 / NDC#: 35192-XXX-XX Manufactured for FacePlace. Made in the U.S.A. Los Angeles, CA 90069 ®FacePlace is a registered trademark. www.faceplace.com	

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UMBRELLA SUNSCREEN

octinoxate titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	3 g in 50 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

BORON NITRIDE (UNII: 2U4T60A6YD)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
SUNFLOWER OIL (UNII: 3W1JG795YI)
ISOMALT (UNII: S870P55O2W)
MACADAMIA OIL (UNII: 515610SU8C)
NIACIN (UNII: 2679MF687A)
PANTHENOL (UNII: WV9CM0O67Z)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPANEDIOL (UNII: 5965N8W85T)
ROSA MOSCHATA OIL (UNII: J99W255AWF)
ROSEMARY (UNII: IJ67X351P9)
SODIUM BENZOATE (UNII: OJ245FE5EU)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TETRASODIUM IMINO DISUCCINATE (UNII: GYS41J2635)
TOCOPHEROL (UNII: R0ZB2556P8)
GRAPE SEED OIL (UNII: 930MLC8XGG)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-013-02	50 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/10/2013	

Labeler - CA-BOTANA INTERNATIONAL (106276728)

Registrant - RODOLFO UGELSTAD (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-BOTANA INTERNATIONAL		106276728	manufacture(35192-013)