

**SUN DEFENSE CANYON RANCH- titanium dioxide, octinoxate emulsion  
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.*

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**Sunscreen Sun Defense Lotion CanyonRanch**

**Active Ingredient**

Titanium Dioxide 5%.....Sunscreen

Octinoxate 4%.....Sunscreen

**Purpose**

Sunscreen

**Ask Doctor**

Stop use and ask a doctor if rash occurs

**Keep out of reach of children**

Keep out of reach of children

**Inactive Ingredients**

Water (Aqua), Glycerine, Glyceryl stearate SE, Cetearyl isononanoate, Coco caprylate, Prunus amygdalus dulcis (Sweet Almond) oil, Mica, Caprylic/Capric triglyceride, Cetyl alcohol, Propanediol, Alanine, Aloe barbadensis leaf extract, Arginine, Ascorbic acid, Ascorbyl palmitate, Bisabolol, Cocos nucifera (Coconut) oil, Glycine, Helianthus annuus (Sunflower) seed oil, Niacin, Olea europaea (Olive) leaf, Panthenol, Phospholipids, Potassium sorbate, Proline, Pentylene glycol, Prunus amygdalus dulcis (Sweet Almond) oil, Rosa canina (Rosehip) oil, Rosmarinus officinalis leaf (Rosemary), Sodium hyaluronate, Sodium citrate, Sorbitan monostearate, Tetrasodium EDTA, Tocopherol, Urea, Vitis vinifera (Grape) seed, Xanthan gum, Citric acid, Ethylhexylglycerin, Phenoxyethanol

**Safety information**

Protect this product from excessive heat and direct sun

**Dosage & Administration**

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 protections 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, specially from 10 a.m.- 2 p.m. Wear long-sleeveshirts, pants, hats, and sunglasses. Protect this product from excessive heat and direct sun.

## 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. If product is swallowed get medical help or contact a poison Control Center right away.

## Indications & Usage

Apply liberally 15 minutes before exposure, use water resistant sunscreen, if swimming or sweating. reapply at least every 2 hours. Children under 6 months: ask a doctor

## Package label

**CANYON RANCH**  
Play outside. Be generous. Protect yourself.  
sun defense lotion  
broad spectrum SPF 30  
473 ml e 16 fl oz

Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Titanium Dioxide 5%.....	Sunscreen
Octinoxate 4%.....	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> • 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.	
<b>Directions</b> • 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 • <b>Sun protection Measures.</b> 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	
<b>Inactive ingredients:</b> Water (Aqua), Glycerine, Glyceryl Stearate SE, Cetearyl Isononanoate, Coco Caprylate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Mica, Caprylic/Capric Triglyceride, Cetyl Alcohol, Propanediol, Alanine, Aloe Barbadensis Leaf Extract, Arginine, Ascorbic Acid, Ascorbyl Palmitate, Bisabolol, Cocos Nucifera (Coconut) Oil, Glycine, Helianthus Annuus (Sunflower) Seed Oil, Niacin, Olea Europaea (Olive) Leaf Extract, Panthenol, Phospholipids, Potassium Sorbate, Proline, Pentylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosa Canina (Rosehip) Oil, Rosmarinus Officinalis Leaf (Rosemary) Extract CO2, Sodium Hyaluronate, Sodium Citrate, Sorbitan Monostearate, Tetrasodium EDTA Tocopherol, Urea, Vitis Vinifera (Grape) Seed Extract, Xanthan Gum, Citric Acid, Ethylhexylglycerin, Phenoxyethanol.	
<b>Other information</b> • Protect this product from excessive heat and direct sun	

CR Operating, LLC NDC 35192-025-09  
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## SUN DEFENSE CANYON RANCH

titanium dioxide, octinoxate emulsion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-025
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	18.92 g in 473 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	23.65 g in 473 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROLINE</b> (UNII: 9DLQ4CIU6V)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ALANINE</b> (UNII: OF5P57N2ZX)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ARGININE, DL-</b> (UNII: FL26NTK3EP)	
<b>NIACIN</b> (UNII: 2679MF687A)	
<b>ROSA MOSCHATA OIL</b> (UNII: J99W255AWF)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CAPRYLIC/CAPRIC MONO/DIGLYCERIDES</b> (UNII: U72Q2I8C85)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)	
<b>GLYCINE</b> (UNII: TE7660XO1C)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	

**Product Characteristics**

<b>Color</b>	white (white yellowish)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-025-09	473 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/15/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/15/2016	

**Labeler** - CA-Botana International (106276728)**Establishment**

Name	Address	ID/FEI	Business Operations
CA-Botana International		106276728	manufacture(35192-025)

Revised: 12/2019

CA-Botana International