

## **OCTINOXATE- octinoxate lotion**

**Hayden Caleel LLC**

*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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### **Drug Facts**

#### **Active ingredients**

Octinoxate 5%

Titanium Dioxide 10%

#### **Purpose**

Sunscreen

#### **Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

#### **Warnings**

##### **For external use only**

**Do not use** on damaged or broken skin.

**When using this product** keep out of the eyes. Rinse with water to remove.

**Stop use and ask a doctor** if skin rash occurs.

**Keep out of reach of children.** If 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 of age: Ask a doctor

#### **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 value 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-sleeved shirts, pants, hats, and sunglasses

#### **Other information**

- protect this product from excessive heat and direct sun

**Inactive ingredients**

Aqua (Water/Eau), Ethylhexyl Palmitate, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Trimellitate, Silica, Cyclopentasiloxane, Caprylic/Capric Triglyceride, HDI/Trimethylol Hexyllactone Crosspolymer, Butylene Glycol, Glycerin, Polyglyceryl-3 Diisostearate, Cyclohexasiloxane, Octyldodecanol, Octyldecyl Xyloside, PEG-30 Dipolyhydroxystearate, Silica Dimethyl Silylate, Phenoxyethanol, Hydroxyethylacrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 60, Caprylyl Glycol, Ethylhexyl Glycerin, Tetrahexyldecyl Ascorbate (Vitamin C), Tocopheryl Acetate (Vitamin E), Polymethylsilsesquioxane, Dimethicone, Retinyl Palmitate (Vitamin A), Triethoxycaprylylsilane, Camellia Oleifera (Green Tea) Leaf Extract, Diamond Powder, (+/-)Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)

**Questions or comments?**

Call: 1.800.232.0398 M-F 9am-6pm MST

**Principal Display Panel - 30 mL Carton Label**

LUXE

LIQUID FOUNDATION

BROAD SPECTRUM SPF 18

ANTI-AGING

DIAMOND POWDER

TECHNOLOGY

glo·minerals

30 mL / 1 fl. oz.

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LIQUID FOUNDATION

BROAD SPECTRUM SPF 18  
ANTI-AGING  
DIAMOND POWDER  
TECHNOLOGY

glō·minerals

30 mL / 1 fl. oz. e

Harness the light-diffusing power of diamond powder technology for a smooth, ageless complexion.

DIRECTIONS: Using Luxe Foundation Brush or your fingers, apply to the face, blending lightly down the neck.

SHAKE WELL AND WIPE  
EXCESS FROM NOZZLE  
WITH EACH USE.



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# OCTINOXATE

octinoxate lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60541-8407
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.05 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Neopentyl Glycol Dicaprylate/Dicaprate (UNII: VLW429K27K)	
Tridecyl Trimellitate (UNII: FY36J270ES)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Glycerin (UNII: PDC6A3C0OX)	
Polyglyceryl-3 Diisostearate (UNII: 46P231QV8)	
Octyldodecanol (UNII: 461N1O614Y)	
Peg-30 Dipolyhydroxystearate (UNII: 9713Q0S7FO)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Dimethicone (UNII: 92RU3N3Y1O)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Silica Dimethyl Silylate (UNII: EU2PSP0G0W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (45000 Mpa.S At 1%) (UNII: 86FQE96TZ4)	
Isohexadecane (UNII: 918X10UF1E)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Ethylhexylglycerin (UNII: 147D247K3P)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Polymethylsilsesquioxane (4.5 Microns) (UNII: 59Z907ZB69)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Camellia Oleifera Leaf (UNII: 5077EL0C60)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Ferric Oxide Red (UNI: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60541-8407-4	1 in 1 BOX		
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2013	

**Labeler** - Hayden Caleel LLC (011367468)

### Establishment

Name	Address	ID/FEI	Business Operations
Hayden Caleel LLC		011367468	MANUFACTURE(60541-8407)

Revised: 8/2013

Hayden Caleel LLC