# BLURRED LINES CC CREME BROAD SPECTRUM SPF 20 SHADE 01 LIGHT- octinoxate, octocrylene, zinc oxide, avobenzone, titanium dioxide cream Color Prevails 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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# Blurred Lines CC Creme Broad Spectrum SPF 20 Shade 01 Light

# **Drug Facts**

#### **Active Ingredients**

Octinoxate 7.5%

Octocrylene 5%

Zinc Oxide 3%

Avobenzone 3%

Titanium Dioxide 1.5%

# **Purpose**

Sunscreen

#### Uses

- Helps prevent sunburn.
- If used as directed with other sun protection decreases the risk of cancer and early skin aging caused by the sun.

#### Warnings

**IFor 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 swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply generously 15 minutes before sun exposure.
- Children under 6 months of age: ask a doctor
- Use a water resistant sunscreen if swimming or sweating.

• Reapply at lease every 2 hours.

#### **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 the product in its container from excessive heat and direct sun

# **Inactive Ingredients**

Water (Aqua), Cyclopentasiloxane, Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Polybutene, Disteardimonium Hectorite, Sodium Chloride, Butylene Glycol, Phenoxyethanol, PEG/PPG-18/18 Dimethicone, Propylene Glycol, Sodium Dehydroacetate, Decylene Glycol, Fragrance/Parfum, Methicone, Disodium EDTA, Tocopheryl Acetate, Lauroyl Lysine, Butylphenyl Methylpropional, Limonene, Geraniol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Linalool. 

[May Contain (+/-):
] Talc, Hydrogen Dimethicone, Aluminum Hydroxide, Iron Oxides (CI 77491, CI 77492, CI 77499).

#### **Product Labels**

(01)





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octinoxate, octocrylene, zinc oxide, avobenzone, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69549-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	30 mg in 1 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	15 mg in 1 mL		

Inactive Ingredients	
Ingredient Name St	trength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
<b>PEG/PPG-18/18 DIMETHICO NE</b> (UNII: 9H0 AO7T794)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM DEHYDRO ACETATE (UNII: 8 W46 YN971G)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
LAURO YL LYSINE (UNII: 113171Q70B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
HYDRO XYISO HEXYL 3-CYCLO HEXENE CARBO XALDEHYDE (UNII: QUE 43B9 Z2Q)	
LINALOOL, (+/-)- (UNII: D81QY6188E)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM HYDRO XIDE (UNII: 5QB0 T2IUN0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69549-001-01	1 in 1 CARTON				
1		30 mL in 1 TUBE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	0 1/17/20 15			

# Labeler - Color Prevails LLC (079427419)

Revised: 1/2015 Color Prevails LLC