

BLURRED LINES CC CREME BROAD SPECTRUM SPF 20 SHADE 02 MEDIUM- 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.

Blurred Lines CC Creme Broad Spectrum SPF 20 Shade 02 Medium

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

☐ **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 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 least 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, Distearidimonium 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



Drug Facts
(continued)

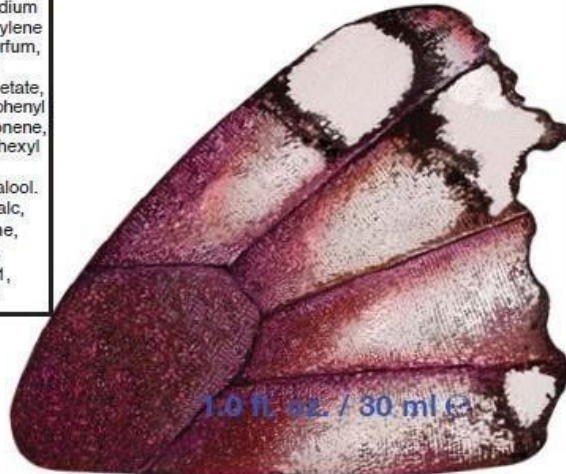
Inactive Ingredients

Water (Aqua), Cyclopentasiloxane, Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Polybutene, Distearidimonium 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).

NONIE CREME
COLOUR PREVAILS

**BLURRED LINES CC CREME
BROAD SPECTRUM SPF 20**

CRÈME CC SPF 20



Drug Facts

Active Ingredients Purpose

Octinoxate 7.5% Sunscreen
 Octocrylene 5% Sunscreen
 Zinc Oxide 3% Sunscreen
 Avobenzone 3% Sunscreen
 Titanium Dioxide 1.5% Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection 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 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.

DIST. BY/PAR: COLOUR PREVAILS, LLC
 NEW YORK, NY 10022

NEW YORK • PARIS • LONDON • WIC • AT • GB

1.800.295.8877
 MADE IN ITALY / FAIT EN ITALIE
 ASSEMBLED IN CHINA / ASSEMBLE EN CHINE
 www.colourprevails.com

Drug Facts
(continued)

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 least 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.

THIS PRODUCT IS NOT TESTED ON ANIMALS.

BLURRED LINES CC CREME BROAD SPECTRUM SPF 20 SHADE 02 MEDIUM

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69549-002
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: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	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 DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
EDETATE DISODIUM (UNII: 7FLD91C86K)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LAUROYL LYSINE (UNII: 113171Q70B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
GERANIOL (UNII: L837108USY)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69549-002-01	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	01/17/2015	

Labeler - Color Prevails LLC (079427419)