

**BOTANICAL SOOTHING SPF-30- octinoxate, octisalate, zinc oxide cream
CONTROL CORRECTIVE SKINCARE INC**

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.

CONTROL CORRECTIVE - BOTANICAL SOOTHING (70764-201)

ACTIVE INGREDIENTS

OCTINOXATE (6.9%)

OCTISALATE (3.0%)

ZINC OXIDE (4.0%)

PURPOSE

SUNSCREEN

USE

A SOOTHING, CALMING AND HYDRATING MOISTURIZER IN ONE. ALSO HELPS TO REDUCE THE APPEARANCE OF SKIN FLUSHING, REDNESS AND VASCULAR STIMULATION. CONTAINING SPF 30 TO FIGHT THE SIGNES OF AGING. A MUST FOR THOSE SUFFERING WITH SKIN AND SUN SENSITIVITIES.

WARNING

FOR EXTERNAL USE ONLY. WHEN USING THIS PRODUCT, AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER. DISCONTINUE USE AND ASK A DOCTOR IF IRRITATION OR RASH DEVELOPS.

DIRECTIONS

APPLY GENEROUSLY WITH FINGERS TO ENTIRE FACE AND NECK. USE DAILY.

SUN ALERT: LIMITING SUN EXPOSURE, WEARING PROTECTIVE CLOTHING, AND USING SUNSCREEN MAY REDUCE THE RISK OF SKIN AGING, SKIN CANCER, AND OTHER HARMFUL EFFECTS OF THE SUN.

INACTIVE INGREDIENTS

WATER, ALOE BARBADENSIS LEAF, GLYCERIN, PROPYLENE GLYCOL, ISOPROPYL PALMITATE, CAPRYLIC/CAPRIC TRIGLYCERIDES, CYCLOPENTASILOXANE, CETEARYL ALCOHOL, CETEARETH-20, VP/EICOSENE COPOLYMER, SQUALANE, POLYSORBATE 60, CYCLOTETRAILOXANE, PHENOXYETHANOL, BUTYROSPERMUM PARKII BUTTER,


PERSEA GRATISSIMA (AVOCADO) OIL, TOCOPHERYL ACETATE, VACCINIUM MYRTILLUS FRUIT/LEAF EXTRACT, SACCHARUM OFFICINARIUM (SUGAR CANE) EXTRACT, ACER SACCHARUM EXTRACT, CITRUS AURANTIUM DULCIS FRUIT EXTRACT, CITRUS LIMON (LEMON) FRUIT EXTRACT, CITRUS GRANDIS SEED EXTRACT, HONEY EXTRACT, CITRIC ACID, PHYTONADIONE, METHYLISOTHIAZOLINONE, RED 33.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

QUESTIONS OR COMMENTS

WWW.CONTROLCORRECTIVE.COM

TOLL FREE 1-866-290-4290 MADE IN USA

<p>DRUG FACTS</p> <table border="0"> <tr> <td>Active Ingredients:</td> <td>Purpose:</td> </tr> <tr> <td>Octinoxate (6.9%)</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate (8.0%)</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide (4.0%)</td> <td>Sunscreen</td> </tr> </table> <p>Use: A soothing, calming and hydrating moisturizer in one. Containing SPF 30 to help fight the signs of aging. A must for those suffering with skin and sun sensitivities.</p> <p>Warning: For external use only. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Discontinue use and ask a doctor if irritation or rash develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions: Apply generously with fingers to entire face and neck. Use Daily.</p> <p>Aplicación: Aplícalo generosamente en toda la cara y cuello. Úsalo diariamente.</p> <p>Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer and other harmful effects of the sun.</p> <p>Inactive Ingredients: Water, Aloe Barbadosensis Leaf, Glycerin, Propylene Glycol, Isopropyl Palmitate, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Cetearyl Alcohol, Ceteareth-20, VP/Eicosene Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Squalane, Polysorbate 60, Cyclohexanone, Phenoxethyl alcohol, Butyrospermum Parkii Shea Butter, Persea Gratissima (Avocado) Oil, Tocopheryl Acetate, Vaccinium Myrtillus Fruit/Leaf Extract, Saccharum Officinarium (Sugar Cane) Extract, Acer Saccharum Extract, Citrus Aurantium Dulcis Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Disodium EDTA, Triethoxycaprylylsilane, Camellia Oleifera Leaf Extract, Citrus Grandis Seed Extract, Honey Extract, Citric Acid, Phytonadione, Methylisothiazolinone, Red 33.</p> <p>Manufactured for: Control Corrective Skincare Questions or Comments: www.controlcorrective.com Toll Free 1-866-290-4290 Made in the USA</p>	Active Ingredients:	Purpose:	Octinoxate (6.9%)	Sunscreen	Octisalate (8.0%)	Sunscreen	Zinc Oxide (4.0%)	Sunscreen	<p>SENSITIVITY/REDNESS</p> <p>WHAT, WHY and HOW?</p> <p>For reddened, inflamed or Rosacea-prone skin. Aloe vera, vitamin E and vitamin A join forces to neutralize the redness. Non-irritating microfine zinc oxide provides full spectrum sunscreen protection.</p>	<p>SENSITIVITY/REDNESS</p>  <p>Control Corrective skincare systems®</p> <p>Botanical Soothing Cream SPF 30 Sunscreen</p> <p>2.5 FL OZ / 74 mL</p>	 <p>When skin throws a tantrum—think everything from Rosacea's flushing redness to irritation's painful inflammation—it's not pretty. For this, Botanical Soothing Cream SPF 30 is the voice of reason as it simultaneously treats, moisturizes and protects over-stimulated skin with calming resolution.</p>
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BOTANICAL SOOTHING SPF-30

octinoxate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70764-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.9 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SHEA BUTTER (UNII: K49155WL9Y)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VACCINIUM MYRTILLUS WHOLE (UNII: EE76EZ4QNZ)	
ACER SACCHARUM WHOLE (UNII: KEG5092LU9)	
CITRUS AURANTIUM FRUIT (UNII: DQD16J2B5O)	
CITRUS LIMON WHOLE (UNII: EEI224A33Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)	
CITRUS MAXIMA SEED (UNII: 083X55C543)	
HONEY (UNII: Y9H1V576FH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PHYTONADIONE (UNII: A034SE7857)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70764-201-52	1 in 1 BOX	06/08/2016	
1	NDC:70764-201-22	74 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 final	part352	06/08/2016	

Labeler - CONTROL CORRECTIVE SKINCARE INC (023999357)

Establishment

Name	Address	ID/FEI	Business Operations
Chemolee Lab Corporation		809982754	manufacture(70764-201)

Revised: 9/2023

CONTROL CORRECTIVE SKINCARE INC