

NATURAL FX - octinoxate, octocrylene, oxybenzone cream
Cover FX Skin Care, 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.

Active Ingredients Section

DRUG FACTS: ACTIVE INGREDIENTS: OCTINOXATE 3.4% w/w, OCTOCRYLENE 2.2% w/w, OXYBENZONE 0.9% w/w

Purpose Section

WATER FRESH FOUNDATION LEAVES SKIN REHYDRATED AND RADIANT LOOKING. REVOLUTIONARY DERMAFIX TECHNOLOGY PROVIDES FLEXIBLE COVERAGE AND ALL DAY WEAR. ENRICHED WITH VITAMIN E TO NOURISH AND PROTECT SKIN FROM DAMAGING FREE RADICALS.

Keep Out Of Reach Of Children Section

Enter section text here

Uses

USES: SUNBURN PROTECTANT SPF 15

THERAPEUTIC BENEFITS: BISBOLOL HELPS REDUCE INFLAMMATION. VITAMIN E NOURISHES AND PROTECTS.

DERMATOLOGISTS 1ST CHOICE OIL FREE FRAGRANCE FREE CONTAINS NON-COMEDOGENIC INGREDIENTS DERMAFIX TECHNOLOGY PROVIDES ALL DAY WEAR

Warning Section

WARNINGS:

THE SUN MAY CAUSE SUNBURN, PREMATURE AGING OF THE SKIN AND SKIN CANCER. AVOIDING THE SUN, WEARING PROTECTIVE CLOTHING AND REGULAR USE OF SUNSCREEN OVER THE YEARS MAY REDUCE THE CHANCE OF THESE HARMFUL EFFECTS.

DISCONTINUE USE IF SKIN IRRITATION DEVELOPS OR INCREASES. IF SKIN IRRITATION PERSISTS, CONTACT A HEALTH CARE PRACTITIONER. AVOID CONTACT WITH EYES.

Directions

DIRECTIONS:

APPLY PRIOR TO SUN EXPOSURE.

Inactive Ingredients

INACTIVE INGREDIENTS:

WATER, CYCLOMETHICONE, DIIOSTEARYL MALATE,POLYGLYCERYL-2

TRISOSTEARATE, NEOPENTYL GLYCOL DICAPRATE, C12-15 ALKYL BENZOATE, BUTYLENE GLYCOL, BIS-PEG/PPG-14/14 DIMETHICONE, TRICONTANYL PVP, SYNTHETIC BEESWAX, CARNAUBA WAX, CETYL PEG/PPG-10/1 DIMETHICONE, MAGNESIUM SILICATE, HYDROGENATED POLYISOBUTENE, CHOLESTERYL HYDROXYSTEARATE, TOCOPHEROL, BISABOLOL, GLYCERYL BEHENATE, TRIETHOXYCAPRYLYL SILANE, SODIUM CHLORIDE, C24-28 ALKYL METHICONE, MAGNESIUM ALUMINUM SILICATE, SORBIC ACID, PHENOXYETHANOL, DEHYDROACETIC ACID, GLYCERYL DIBEHENATE, SALICYCLIC ACID, TRIBEHENIN, BENZOIC ACID, BENZYL ALCOHOL, BENZETHONIUM CHLORIDE, BHT

MAY CONTAIN:

TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499), CHROMIUM OXIDE GREENS (CI 77288)

Product Label

NATURAL FX

WATER BASED
FOUNDATION

SPF 15 FPS
DIN 02248412

30Ml/1.0 fl oz

WATER FRESH FOUNDATION LEAVES SKIN REHYDRATED AND RADIANT LOOKING. REVOLUTIONARY DERMAFIX TECHNOLOGY PROVIDES FLEXIBLE COVERAGE AND ALL DAY WEAR. ENRICHED WITH VITAMIN e TO NOURISH AND PROTECT SKIN FROM DAMAGING FREE RADICALS.

WARNING: CONTAINS BENZOPHENONE-3 PLEASE RECYCLE

COVER FX

DIST. BY/PAR

COVER FX SKIN CARE INC.

TORONTO, ONTARIO

CANADA M3J 2W8. LONDON W1V 2LD

MADE IN/FABRIQUÉ AU CANADA

WWW.COVERFX.COM

DERMATOLOGISTS 1ST CHOICE

· OIL FREE · FRAGRANCE FREE · CONTAINS NON-COMEDOGENIC INGREDIENTS

· DERMAFIX TECHNOLOGY PROVIDES ALL DAY WEAR

THERAPEUTIC BENEFITS:

BISABOLOL HELPS REDUCE INFLAMMATION. VITAMIN E NOURISHES AND PROTECTS. SHAKE WELL BEFORE USE.

YOU MAY REPORT A SERIOUS ADVERSE EFFECT FROM USE OF THIS PRODUCT TO (USA)
COVER FX 33 ELM STREET, SUITE 377, CHAMPLANE, NY 12919

(CANADA) COVER FX, 1681 FLINT RD, TORONTO, ON M3J 2W8

WATER FRESH FOUNDATION LEAVES SKIN
REHYDRATED AND RADIANT LOOKING.
REVOLUTIONARY DERMAFIX TECHNOLOGY
PROVIDES FLEXIBLE COVERAGE & ALL DAY WEAR.
ENRICHED WITH VITAMIN E TO NOURISH AND
PROTECT SKIN FROM DAMAGING FREE RADICALS.
FORMULE À BASE D'EAU QUI HYDRATE LA PEAU
ET LUI DONNE UN ASPECT LISSE ET RADIEUSE.
ISSU DE LA TECHNOLOGIE RÉVOLUTIONNAIRE
DERMAFIX QUI PROCURE UNE COUVRANCE
OPTIMALE ET UNE LONGUE TENUE.
ENRICHÉ DE VITAMINE E POUR NOURRIR LA PEAU
ET LA PROTÉGER CONTRE LES RADICAUX LIBRES.

SHAKE WELL BEFORE USE.

BIEN AGITER AVANT USAGE.

ACTIVE INGREDIENTS/INGRÉDIENTS ACTIFS:
OCTINOXATE 3.4% w/w, OCTOCRYLENE 2.2% w/w,
OXYBENZONE 0.9% w/w

WARNING: CONTAINS BENZOPHENONE-3



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PRODUCT TO/AFIN DE SIGNALER TOUT EFFET INDESIRABLE MAJEUR
ASSOCIÉ À CE PRODUIT, CONTACTEZ:
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(CANADA) COVER FX, 1681 FLINT RD, TORONTO, ON M3J 2W8

NATURAL **FX**

WATER BASED
FOUNDATION
FOND DE TEINT
LIQUIDE À BASE D'EAU
SPF 15 FPS
DIN 02248412

30 mL/1.0 FLOZ e

PLEASE RECYCLE
SYN RECYCLES

NO ANIMAL TESTING
NON TESTE SUR LES
ANIMAUX

DRUG FACTS/FAITS PHARMACOLOGIQUES
 ACTIVE INGREDIENTS/INGRÉDIENTS ACTIFS:
 OCTINOXATE 3.4% w/w, OCTOCRYLENE 2.2% w/w,
 OXYBENZONE 0.9% w/w
USES/USAGES: SUNBURN PROTECTANT SPF 15
 FACTEUR DE PROTECTION SOLAIRE FPS 15
WARNINGS/AVERTISSEMENTS:
 THE SUN MAY CAUSE SUNBURN, PREMATURE
 AGING OF THE SKIN AND SKIN CANCER.
 AVOIDING THE SUN, WEARING PROTECTIVE
 CLOTHING AND REGULAR USE OF SUNSCREENS
 OVER THE YEARS MAY REDUCE THE CHANCE OF
 THESE HARMFUL EFFECTS.
 LE SOLEIL PEUT CAUSER DES COUPS DE SOLEIL,
 UN VIEILLESSEMENT PRÉCOCÉ DE LA PEAU ET
 LE CANCER DE LA PEAU. LE FAIT D'ÉVITER
 L'EXPOSITION AU SOLEIL, LE PORT DE VÊTEMENTS
 PROTÉGÉS ET L'USAGE RÉGULIÈRE D'ÉCRANS
 SOLAIRES PEUT, AVEC LES ANNÉES, RÉDUIRE LE
 RISQUE DE CES EFFETS NOCIFS.
 DISCONTINUE USE IF SKIN IRRITATION DEVELOPS
 OR INCREASES. IF IRRITATION PERSISTS, CONSULT
 A HEALTH CARE PRACTITIONER. AVOID CONTACT
 WITH EYES.
 CESSER D'UTILISER SI UNE IRRITATION DE LA
 PEAU SE DÉVELOPPE OU DEVIENT PLUS SÉVÈRE.
 SI L'IRRITATION PERSISTE, CONSULTER UN
 PRATICIEN DE SOINS DE SANTÉ. ÉVITER TOUT
 CONTACT AVEC LES YEUX.
DIRECTIONS/MODE D'EMPLOI:
 APPLY PRIOR TO SUN EXPOSURE.
 APPLIQUER AVANT L'EXPOSITION AU SOLEIL.
INACTIVE INGREDIENTS/INGRÉDIENTS INACTIFS:
 AQUA, CYCLOMETHICONE, DISOSTEARYL MALATE,
 POLYGLYCERYL-2 TRISOSTEARATE, NEOPENTYL
 GLYCOL DICAPRATE, C12-15 ALKYL BENZOATE,
 BUTYLENE GLYCOL, BIS-PEG/PPG-14/14 DIMETH-
 ICONE, TRICONTANYL PVR SYNTHETIC BEESWAX,
 CARNAUBA WAX, CETYL PEG/PPG-10/1 DIMETH-
 ICONE, MAGNESIUM SILICATE, HYDROGENATED
 POLYISOBUTENE, CHOLESTERYL HYDROXYSTEARATE,
 TOCOPHEROL, BISBOLOL, GLYCERYL BEHENATE,
 TRIETHOXYCAPRYLYL SILANE, SODIUM CHLORIDE,
 C24-28 ALKYL METHICONE, MAGNESIUM ALUMINUM
 SILICATE, SORBIC ACID, PHENOXYETHANOL,
 DEHYDROACETIC ACID, GLYCERYL DIBEHENATE,
 SALICYLIC ACID, TRIBENHIN, BENZOIC ACID,
 BENZYL ALCOHOL, BENZETHONIUM CHLORIDE, BHT
MAY CONTAIN/PEUT CONTENIR:
 TITANIUM DIOXIDE (CI 77891), IRON OXIDES
 (CI 77491, CI 77492, CI 77499), CHROMIUM OXIDE
 GREENS (CI 77288)

DERMATOLOGISTS 1ST CHOICE
 • OIL FREE - FRAGRANCE FREE - CONTAINS NON-COMEDOGENIC INGREDIENTS
 • DERMAFIX TECHNOLOGY PROVIDES ALL DAY WEAR
THERAPEUTIC BENEFITS:
 BISBOLOL HELPS REDUCE INFLAMMATION. VITAMINE E NOURISHES AND PROTECTS.
 SHAKE WELL BEFORE USE.



WATER BASED
 FOUNDATION
 FOND DE TEINT
 LIQUIDE À BASE D'EAU
 SPF 15 FPS
 DIN 02248412

30 mL / 1.0 FL OZ e

LE 1ER CHOIX DES DERMATOLOGUES
 • SANS HUILE - SANS PARFUM - CONTIENT DES INGRÉDIENTS NON COMÉDOGÈNES
 • LA TECHNOLOGIE DERMAFIX PROCURE UNE LONGUE TENUE
AVANTAGES THÉRAPEUTIQUES:
 LE BISBOLOL AIDE À RÉDUIRE L'INFLAMMATION. LA VITAMINE E NOURRIT ET PROTÈGE.
 BIEN AGITER AVANT USAGE.

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NATURAL FX
 octinoxate, octocrylene, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68327-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.4 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.2 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
HYDROGENATED POLYBUTENE (370 MW) (UNII: V5H8103878)	
CHOLESTERYL HYDROXYSTEARATE (UNII: O6K1LG6N4D)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LEVOMENOL (UNII: 24WE03BX2T)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SORBIC ACID (UNII: X045WJ989B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHROMIC OXIDE (UNII: X5Z09SU859)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68327-002-01	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	08/01/2012	

Labeler - Cover FX Skin Care, Inc. (202908021)

Registrant - Cover FX Skin Care, Inc. (202908021)

Revised: 2/2013

Cover FX Skin Care, Inc.