

BRITEPREP FX - octocrylene, octinoxate, oxybenzone, titanium dioxide 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 Ingredient Section

ACTIVE INGREDIENTS: OCTOCRYLENE - 9.0% w/w, OCTINOXATE 7.5% w/w,
OXYBENZONE 3.0% w/w, TITANIUM DIOXIDE 1.5% w/w

Purpose Section

BRIGHTENING FOUNDATION PRIMER SPF 50

PRIME YOUR SKIN WITH THIS CREAM BALM PRIMER, TO IMPROVE BLENDING AND WEAR. DERMAVEIL BLURS THE APPEARANCE OF FINE LINES AND PORES, WHILE ILLUMINATING SKIN. BEARBERRY EXTRACT HELPS REDUCE THE APPEARANCE OF AGE SPOTS BY BRIGHTENING THE SKIN. TEPRENONE AND PEPTIDES PROMOTES YOUTHFUL LOOKINGSKIN. SWEET BLACK TEA MOISTURIZES THE SKIN TO LOOK STRENGTHENED, FIRM AND PLUMP.

Warnings Section

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

WARNINGS: CONTAINS BENZOPHENONE - 3

CAUTION: DISCONTINUE USE IF SKIN IRRITATION DEVELOPS OR INCREASES. IF IRRITATION PERSISTS, CONSULT A HEALTH CARE PRACTITIONER.

Report Section

YOU MAY REPORT A SERIOUS ADVERSE AFFECT FROM USE OF THIS PRODUCT TO (USA) COVER FX, 33 ELM STREET, SUITE 377, CHAMPLAIN, NY 12919 9CANADA) COVER FX, 1681 FLINT RD, TORONTO, ON M3J 2W8

Keep Out of Reach of Children Section

Enter section text here

Uses Section

Uses: SUNBURN PROTECTANT SPF 50. PROTECTS AGAINST UVA/UVB RAYS.

Directions Section

DIRECTIONS: APPLY PRIOR TO SUN EXPOSURE
SHAKE WELL BEFORE USE

Inactive Ingredients Section

INACTIVE INGREDIENTS: CYCLOPENTASILOXANE, AQUA, HYDROGENATED POLYISOBUTENE, GLYCERIN, POLYETHYLENE, CAPRYLIC/CAPRIC TRIGLYCERITE, C12-15 ALKYL BENZOATE, SACCHAROMYCES/XYLINUM BLACK TEA FERMENT, SILICA, DIMETHICONE CROSSPOLYMER, CETYL PEG/PPG-10/1 DIMETHICONE, SQUALANE, MICA, GLYCERYL DIBEHENATE, ALOE BARBADENSIS LEAF JUICE, ASCORBYL GLUCOSIDE, BISABOOL, BUTYROSPERMUM PARKII (SHEA BUTTER), CETYL DIMETHICONE, OCTADECANOIC ACID, TOCOPHERYL ACETATE, TITANIUM DIOXIDE, SODIUM CHLORIDE, BUTYLENE GLYCOL, TRIBEHENIN, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, TIN OXIDE, ALUMINA, ARCTOSTAPHYLOS UVA URSI (BEARBERRY) EXTRACT, DIMETHICONOL, ISOPROPYL TITANIUM TRIISOSTEARATE/TRIETHOXYCARYLSILANE CROSSPOLYMER, POLYHYDROXYSTEARIC ACID, BENZYL ALCOHOL, LINOLEIC ACID, LINOLENIC ACID, RETINYL PALMITATE, TEPRENONE, ARTEMIA (PLANKTON) EXTRACT, BENZOIC ACID, HYDROXYETHYLCELLULOSE, CARBOMER, POLYSORBATE 20, SORBIC ACID, CITRUS AURANTIUM (NEROLI), PALMITOYL OLIGOPEPTIDE, PALMITOYL TETRAPEPTIDE-7

Package Label Section

BRITE PREP FX BRIGHTENING FOUNDATION PRIMER SPF 50

30 mL/1.0 FL OZ e CREAM

DERMATOLOGISTS FIRST CHOICE

CRUELTY FREE

SUSTAINABLE FORESTRY INITIATIVE Certified Chain of Custody Promoting Sustainable Forest Management www.sfiprogram.org

COVER FX DIST. BY/ COVER FX SKIN CARE INC. TORONTO, ONTARIO CANADA M3J 2W8. LONDON W1V 2LD WWW.COVERFX.COM

PRIME YOUR SKIN WITH THIS CREAM BALM
PRIMER, TO IMPROVE BLENDING AND WEAR.
DERMAVEIL BLURS THE APPEARANCE OF FINE
LINES & PORES, WHILE ILLUMINATING SKIN.
BEARBERRY EXTRACT HELPS REDUCE THE APPEARANCE
OF AGE SPOTS BY BRIGHTENING THE SKIN.

PRÉPAREZ VOTRE PEAU AVEC CE RICHE BALME
CRÉMELIX QUI FACILITE L'APPLICATION ET
PROLONGE LA TENUE DU FOND DE TEINTE.
DERMAVEIL ATTÉNUÉ L'APPEARANCE DES RIDULES
ET DES PORES, ET ILLUMINE LE TEINT.

EXTRAIT DE BEARBERRY AIDE À DIMINUER
L'APPEARANCE DES TACHES DE MEILLISSEMENT
EN ECLAIRCISSANT LA PEAU.

**SHAKE WELL BEFORE USE
BIEN AGITER AVANT USAGE.**

ACTIVE INGREDIENTS/INGRÉDIANTS ACTIFS:
OCTOCRYLENE 9.0% w/w OCTINOXATE 7.5% w/w
OXYBENZONE 3.0% w/w TITANIUM DIOXIDE 1.5% w/w
WARNING: CONTAINS BENZOPHENONE-3



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

YOU MAY REPORT A SERIOUS ADVERSE EFFECT FROM USE OF THIS
PRODUCT TO/AFIN DE SIGNALER TOUT EFFET INDÉSIRABLE MAJEUR
ASSOCIÉ À CE PRODUIT, CONTACTEZ:

(USA) COVER FX, 33 ELM STREET, SUITE 377, CHAMPLAIN, NY 12919
(CANADA) COVER FX, 1681 FLINT RD, TORONTO, ON M3J 2W8

**BRITE
PREP**

BRIGHTENING
FOUNDATION PRIMER
BASE ÉCLAT
SPF 50 FPS

DIN 02323095

30 mL/1.0 FL OZ
CREAM/CRÈME



PRIME YOUR SKIN WITH THIS CREAM BALM PRIMER, TO IMPROVE BLENDING AND WEAR. DERMAVEIL BLURS THE APPEARANCE OF FINE LINES & PORES, WHILE ILLUMINATING SKIN. BEARBERRY EXTRACT HELPS REDUCE THE APPEARANCE OF AGE SPOTS BY BRIGHTENING THE SKIN. TEPRENONE AND PEPTIDES PROMOTES YOUTHFUL LOOKINGSKIN. SWEET BLACK TEA MOISTURIZES THE SKIN TO LOOK STRENGTHENED, FIRM AND PLUMP.

PRÉPAREZ VOTRE PEAU AVEC CE RICHE BAUME CRÉMEUX QUI FACILITE L'APPLICATION ET PROLONGE LA TENUE DU FOND DE TEINT. DERMAVEIL ATTÈNE L'APPARENCE DES RIDULES ET DES PORES, ET ILLUMINE LE TEINT. EXTRAIT DE BEARBERRY AIDE À DIMINUER L'APPARENCE DES TACHES DE VIEILLESSEMENT EN ÉCLAIRCISSANT LA PEAU. LE TEPRENONE ET LES PEPTIDES FAVORISENT UNE PEAU D'ALLURE JEUNE DE LA PEAU. LE SWEET BLACK TEA HYDRATE LA PEAU POUR LUI DONNER UN ASPECT RENFORCÉ, FERME ET BRIGHTENING REBONDI.

DIRECTIONS/MODE D'EMPLOI:
APPLY PRIOR TO SUN EXPOSURE.
APPLIQUER AVANT L'EXPOSITION AU SOLEIL.

SHAKE WELL BEFORE USE
BIEN AGITER AVANT USAGE

**INACTIVE INGREDIENTS/
INGRÉDIENTS INACTIFS:**

CYCLOPENTASILOXANE, AQUA, HYDROGENATED POLYISOBUTENE, GLYCERIN, POLYETHYLENE, CAPRYLIC/CAPRIC TRIGLYCERIDE, C12-15 ALKYL BENZOATE, SACCHARONYCES/OXYLINUM BLACK TEA FERMENT, SILICA, DIMETHICONE CROSSPOLYMER, CETYL PEG-7/PPG-10/1 DIMETHICONE, SQUALANE, MICA, GLYCERYL DIBENATE, ALOE BARBADENSIS LEAF JUICE, ASCORBYL GLUCOSIDE, BISABOLOL, BUTYROSPERMUM PARKII (SHEA BUTTER), CETYL DIMETHICONE, OCTADECENEDIOLIC ACID, TOCOPHERYL ACETATE, TITANIUM DIOXIDE, SODIUM CHLORIDE, BUTYLENE GLYCOL, TRIBENHIN, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, TIN OXIDE, ALUMINA, ARCTOSTAPHYLOS UVA URSI (BEARBERRY) EXTRACT, DIMETHICANOL, ISOPROPYL TITANIUM TRISOSTEARATE/TRIETHOXYCAPRYLYLSILANE CROSSPOLYMER, POLYHYDROXY-STEARIC ACID, BENZYL ALCOHOL, LINOLEIC ACID, LINOLENIC ACID, RETINYL PALMITATE, TEPRENONE, ARTEMIA (PLANKTON) EXTRACT, BENZOIC ACID, HYDROXYETHYLCELLULOSE, CARBOMER, POLYSORBATE 20, SORBIC ACID, CITRUS AURANTIUM (NEROLI), PALMITOYL OLIGOPEPTIDE, PALMITOYL TETRAPEPTIDE-7



CRUELTY FREE
SANS CRUAUTÉ



DIST. BY/PAR
COVER FX SKIN CARE INC.
TORONTO, ONTARIO
CANADA M3J 2W8.
LONDON W1V 2LD
MADE IN/FABRIQUÉ
AU CANADA
WWW.COVERFX.COM

**BRITE
PREP**

BRIGHTENING
FOUNDATION PRIMER
BASE ÉCLAT
SPF 50 FPS
DIN 02323095
30 mL/1.0 FLOZ e
CREAM/CRÈME

**ACTIVE INGREDIENTS/
INGRÉDIENTS ACTIFS:**
OCTOCRYLENE 9.0% w/w
OCTINOXATE 7.5%w/w
OXYBENZONE 3.0%w/w
TITANIUM DIOXIDE 1.5% w/w

USAGES/USAGES:
SUNBURN PROTECTANT SPF 50.
PROTECTS AGAINST UVA/UVB RAYS.
FACTEUR DE PROTECTION SOLAIRE
FPS 50. PROTÈGE CONTRE LES RAYONS
UVA ET UVB

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 PRÉMATURÉ 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 RÉGULIER DE CRÈMES SOLAIRES
PEUT, AVEC LES ANNÉES, RÉDUIRE LE
RISQUE DE CES EFFETS NOCIFS.
WARNING: CONTAINS BENZOPHENONE-3

CAUTION:
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.

YOU MAY REPORT A SERIOUS ADVERSE
AFFECT FROM USE OF THIS PRODUCT TO:
AFIN DE SIGNALER TOUT EFFET INDÉSIRABLE
MAJEUR ASSOCIÉ À CE PRODUIT, CONTACTEZ:
(USA) COVER FX, 33 ELM STREET, SUITE 377,
CHAMPLAIN, NY 12919
(CANADA) COVER FX, 1681 FLINT RD,
TORONTO, ON M3J 2W8



BRITEPREP FX

octocrylene, octinoxate, oxybenzone, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68327-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
WATER (UNII: 059QF0KO0R)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TEA LEAF (UNII: GH42T47V24)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3.7) (UNII: 8INO2K35FA)	
SQUALANE (UNII: GW89575KF9)	
MICA (UNII: V8A1AW0880)	
GLYCERYL 1,2-DIBEHENATE (UNII: 21E45121YS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
LEVOMENOL (UNII: 24WE03BX2T)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OCTADECENEDIOIC ACID (UNII: 565ZMT5QRG)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LINOLENIC ACID (UNII: 0RBV727H71)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TEPRENONE (UNII: S8S8451A4O)	
BRINE SHRIMP (UNII: 3ID50N77DH)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBIC ACID (UNII: X045WJ989B)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68327-005-01	30 mL in 1 TUBE		
2	NDC:68327-005-02	15 mL in 1 TUBE		
3	NDC:68327-005-03	5 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/01/2010	

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

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

Revised: 2/2013

Cover FX Skin Care, Inc.