

**SKIN TINT FX - octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide 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.*

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**Active Ingredients**

**DRUG FACTS**

**ACTIVE INGREDIENTS:**

OCTINOXATE 6.50% w/w, OCTISALATE 3.50% w/w, OXYBENZONE 2.10% w/w, TITANIUM DIOXIDE 5.50% w/w, ZINC OXIDE 5.50% w/w

**Purpose**

USES: SUNBURN PROTECTANT SPF 30

**Keep Out of Reach of Children**

**Use**

SUNBURN PROTECTANT SPF 30

NATURAL PEARLIZED MINERALS PROVIDE A HINT OF COLOUR TO ENHANCE THE APPEARANCE OF SUN KISSED RADIANCE AND TONE.

INFUSION OF PEPTIDES, CERAMIDES, AND F.A.C.E MULTI-VITAMINS HELPS REJUVENATE, NOURISH, HYDRATE AND PROTECT SKIN. HYALURONIC SPHERES SWELL WITH CAPTURED WATER AND TIME-RELEASED MOISTURE BACK INTO THE SKIN.

**Warnings**

WARNINGS: THE SUN MAY CAUSE PREMATURE AGING OF THE SKIN AND SKIN CANCER.

AVOID THE SUN, WEARING PROTECTIVE CLOTHING AND REGULAR USE OF SUNSCREENS OVER THE YEARS MAY REDUCE THE CHANCE OF THESE HARMFUL EFFECTS.

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.

**You may report**

YOUR MAY REPORT A SERIOUS ADVERSE AFFECT FROM THE USE OF THIS PRODUCT TO:

(USA) COVER FX, 33 ELM STREET, SUITE 377, CHAMPLAIN, NY 12919

**Directions**

DIRECTIONS:

APPLY PRIOR TO SUN EXPOSURE.

SHAKE WELL BEFORE USAGE

**Inactive Ingredients**

INACTIVE INGREDIENTS:

CYCLOPENTASILOXANE, DIMETHICONE CROSSPOLYMER, ETHYLHEXYL PALMITATE, SQUALANE, TRIDECYL TRIMELLITATE, DIMETHICONE /VINYL DIMETHICONE CROSSPOLYMER, BIS-PEG/PPG-14/14 DIMETHICONE, C 12-15 ALKYL BENZOATE, MICA, CETYL PEG/PPG-10/1 DIMETHICONE, DISTEARDIMONIUM HECTORITE, BISABOLOL, TOCOPHEYL ACETATE, DIMETHICONOL, SILIA, ALUMINA, TRIIBEHENIN, BENZYL ALCOHOL, DIMETHICONE/METHICONE COPOLYMER, PHENOXYETHANOL, GLYCERIN, LINOLEIC ACID, LINOLENIC ACID, TETRAHEXYLDECYL ASCORBATE, PEG/PPG-20/15 DIMETHICONE, SILICA, DIMETHYL SILYLATE, CERAMIDE-2, BENZOIC ACID, PEG-10 RAPESEED STEROL, BUTYLENE GLYCOL, TRIETHOXYCAPYLSILANE, RETINYL PALMITATE, SORBIC ACID, DEHYDROACETIC ACID, CAPRYLYL GLYCOL, LAVANDULA ANGUSTIFOLIA (LAVENDER), HEXYLENE GLYCOL, SODIUM HYALURONATE, PALM OLIGOPEPTIDE

MAY CONTAIN:

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

**Package Label**

SKIN TINT FX

MOISTURIZING TREATMENT AND TINT

SPF 30 FPS DIN 02295156 30Ml/1.0 fl oz

OIL FREE, WAX FREE, FRAGRANCE FREE, AND PARABEN FREE.

CRUELTY FREE

Cover Fx

FACEBOOK.COM/COVERFX SUSTAINABLE FORESTRY INITIATIVE Certified Chain of Custody Promoting Sustainable Forest Management [www.sfprogram.org](http://www.sfprogram.org)

COVER FX

DIST. BY COVER FX SKIN CARE INC. TORONTO, ONTARIO CANADA M3J 2W8. LONDON W1V 2LD MADE IN FABRIQUE AU CANADA

WWW.COVERFX.COM

NATURAL PEARLIZED MINERALS  
PROVIDE A HINT OF COLOUR TO ENHANCE  
THE APPEARANCE OF SUN KISSED  
RADIANCE AND TONE.  
INFUSION OF PEPTIDES, CERAMIDES AND  
F.A.C.E MULTI-VITAMINS HELPS REJUVENATE,  
NOURISH, HYDRATE AND PROTECT SKIN.  
MINÉRAUX NATURELS PERLÉS  
AJOUTENT UN SOUPÇON DE COULEUR  
QUI DONNENT UN TEINT RADIEUX  
LÉGÈREMENT HÂLÉ.  
UNE INFUSION DE PEPTIDES, DE CÉRAMIDES  
ET DE MULTIVITAMINES F.A.C.E. AIDENT  
À RAJEUNIR, À NOURRIR, À HYDRATER  
ET À PROTÉGER LA PEAU.

SHAKE WELL BEFORE USE.  
BIEN AGITER AVANT USAGE.  
ACTIVE INGREDIENTS/INGRÉDIENTS ACTIFS:  
OCTINOXATE 6.50% w/w, OCTISALATE  
3.50% w/w, OXYBENZONE 2.10% w/w,  
TITANIUM DIOXIDE 5.50% w/w,  
ZINC OXIDE 5.50% w/w  
WARNING: CONTAINS BENZOPHENONE-3



COVER **FX**®

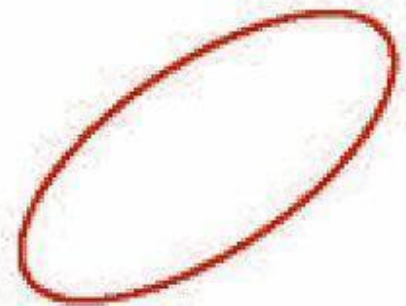
DIST. BY/PAR  
COVER FX SKIN CARE INC.  
TORONTO, ONTARIO  
CANADA M3J 2W8. LONDON W1V 2LD  
MADE IN/FABRIQUÉ AU CANADA  
WWW.COVERFX.COM

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

SKIN  
TINT 

MOISTURIZING  
TREATMENT & TINT  
SOIN HYDRATANT  
TEINTÉ  
SPF 30 FPS  
DIN 02295156

30 mL/1.0 FL OZ e





NATURAL PEARLIZED MINERALS PROVIDE A HINT OF COLOUR TO ENHANCE THE APPEARANCE OF SUN KISSED RADIANCE AND TONE. INFUSION OF PEPTIDES, CERAMIDES AND F.A.C.E MULTI-VITAMINS HELPS REJUVENATE, NOURISH, HYDRATE AND PROTECT SKIN. HYALURONIC SPHERES SWELL WITH CAPTURED WATER AND TIME-RELEASE MOISTURE BACK INTO THE SKIN. OIL FREE, WAX FREE, FRAGRANCE FREE AND PARABEN FREE.

DES MINÉRAUX NATURELS PERLÉS AJOUTENT UN SOUPÇON DE COULEUR QUI DONNENT UN TEINT RADIEUX LÉGÈREMENT HÂLÉ.

UNE INFUSION DE PEPTIDES, DE CÉRAMIDES ET DE MULTIVITAMINES F.A.C.E. AIDENT À RAJEUNIR, A NOURRIR, À HYDRATER ET À PROTÉGER LA PEAU.

DES SPHÈRES HYALURONIQUES SE GORGENT D'EAU ET LIBÈRENT LENTEMENT CETTE RÉSERVE D'EAU DANS LA PEAU.

NE CONTIENT PAS D'HUILE, DE CIRE, DE PARFUM NI DE PARABÈNE.

**DIRECTIONS/MODE D'EMPLOI:**  
APPLY PRIOR TO SUN EXPOSURE.  
APPLIQUEZ AVANT L'EXPOSITION AU SOLEIL.  
SHAKE WELL BEFORE USE.  
BIEN AGITER AVANT USAGE.

**INACTIVE INGREDIENTS/  
INGRÉDIENTS INACTIFS:**  
CYCLOPENTASILOXANE, DIMETHICONE  
CROSSPOLYMER, ETHYLHEXYL PALMITATE,  
SQUALANE, TRIDECYL TRIMELLITATE,  
DIMETHICONE/VINYL DIMETHICONE  
CROSSPOLYMER, BIS-PEG/PPG-14/14  
DIMETHICONE, C-12-15 ALKYL BENZOATE,  
MICA, CETYL PEG/PPG-10/1 DIMETHICONE,  
DISTEARDIMONIUM HECTORITE, BISABOLOL,  
TOCOPHERYL ACETATE, DIMETHICONOL,  
SILICA, ALUMINA, TRIBENHIN, BENZYL  
ALCOHOL, DIMETHICONE/ETHICONE  
COPOLYMER, PHENOKYETHANOL,  
GLYCERIN, LINOLEIC ACID, LINOLENIC ACID,  
TETRAHEXYLDECYL ASCORBATE,  
PEG/PPG-20/15 DIMETHICONE, SILICA  
DIMETHYL SILYLATE, CERAWIDE 2, BENZOIC  
ACID, PEG-10 RAPESEED STEROL, BUTYLENE  
GLYCOL, TRIETHOXYCAPRYLYLSILANE,  
RETINYL PALMITATE, SORBIC ACID,  
DEHYDROACETIC ACID, CAPRYLYL GLYCOL,  
LAVANDULA ANGUSTIFOLIA (LAVENDER),  
HEXYLENE GLYCOL, SODIUM HYALURONATE,  
PALMITOYL OLIGOPEPTIDE

**MAY CONTAIN/PEUT CONTENIR:**  
TITANIUM DIOXIDE (CI 77891),  
IRON OXIDES (CI 77491, CI 77492, CI 77499),  
CHROMIUM OXIDE GREENS (CI 77288)



**CRUELTY FREE  
SANS CRUAUTÉ**



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COVER FX SKIN CARE INC.  
TORONTO, ONTARIO  
CANADA M3J 2W8.  
LONDON W1V 2LD  
MADE IN/FABRIQUÉ  
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**SKIN  
TINT**

**MOISTURIZING  
TREATMENT & TINT  
SOIN HYDRATANT  
TEINTÉ  
SPF 30 FPS  
DIN 02295156  
30 mL/1.0 FLOZ e**

**DRUG FACTS/FAITS PHARMACOLOGIQUES**

**ACTIVE INGREDIENTS/  
INGRÉDIENTS ACTIFS:**  
OCTINOXATE 6.50% w/w, OCTISALATE  
3.50% w/w, OXYBENZONE 2.10% w/w,  
TITANIUM DIOXIDE 5.50% w/w,  
ZINC OXIDE 5.50% w/w

**USES/USAGES:** SUNBURN PROTECTANT SPF 30  
FACTEUR DE PROTECTION SOLAIRE FPS 30

**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 VIEILLISSEMENT PRÉMATURÉ  
DE LA PEAU ET LE CANCER DE LA PEAU.  
LE FAIT D'ÉVITER L'EXPOSITION AU  
SOLEIL, LE PORT DE VÊTEMENTS  
PROTECTEURS ET L'USAGE RÉGULIER  
D'ÉCRANS 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 PRACTICIEN 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



**SKIN TINT FX**

octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68327-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3.5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	2.1 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	5.5 g in 100 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.5 g in 100 mL
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## Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SQUALANE (UNII: GW89575KF9)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
LEVOMENOL (UNII: 24WE03BX2T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONOL (41 MPAS) (UNII: 343C7U75XW)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LINOLENIC ACID (UNII: 0RBV727H71)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PEG/PPG-20/15 DIMETHICONE (UNII: 06R6X77P9C)	
CERAMIDE 2 (UNII: C04977SRJ5)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SORBIC ACID (UNII: X045WJ989B)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
SILICA DIMETHYL SILYLATE (UNII: EU2PS0G0W)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68327-003-01	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	09/20/2011	

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

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

Revised: 2/2013

Cover FX Skin Care, Inc.