

MINT GLAZE FX - octinoxate, oxybenzone ointment
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; OCTINOXATE 7.5% w/w OXYBENZONE 2.5% w/w

Purpose Section

MOISTURIZING LIP TREAT-MINT PRIMER SPF 15

THIS PROTECTIVE FORTIFYING AND FRESHENING GLAZED BALM MAINTAINS YOUTHFUL LOOKING LIPS.

USE AS A POUT PERFECTING PRIMER TO SOFTEN THE APPEARANCE OF LINES AND HYDRATE LIPS.

Keep Out of Reach of Children Section

KEEP OUT OF REACH OF CHILDREN

Uses Section

USES: SUNBURN PROTECTANT SPF 15

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. DISCONTINUE USE IF SKIN IRRITATION DEVELOPS OR INCREASES. IF IRRITATION PERSISTS, CONSULT A HEALTH CARE PRACTITIONER. FOR EXTERNAL USE ONLY.

Directions Section

DIRECTIONS APPLY PRIOR TO SUN EXPOSURE. REAPPLY AS NEEDED OR AFTER EATING AND DRINKING.

Inactive Ingredient Section

INACTIVE INGREDIENTS: HYDROGENATED POLYISOBUTENE, POLYGLYCERYL-2 TRIISOSTEARATE, TRIDECYL TRIMELLITATE, CYCLOPENTASILOXANE, POLYETHYLENE, C10-30 CHOLESTEROL/LANOSTEROL ESTERS, BUTYROSPERMUM PARKII (SHEA BUTTER), DIPALMITOYL HYDROXYPROLINE, MENTHA PIPERITA (PEPPERMINT), ETHYLHEXYL PALMITATE, TOCOPHERYL ACETATE, CHOLESTERYL HYDROXYSTEARATE, TETRAHEXYLDECYL ASCORBATE, LINOLEIC ACID, LINOLENIC ACID, TRIBEHENIN, SORBITAN ISOSTERATE, SILICA DIMETHYL Silylate, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, PHENOXYETHANOL, HEXYLENE GLYCOL, SODIUM HYALURONATE, PALMITOYL OLIGOPEPTIDE, SILICA, TIN OXIDE

MAY CONTAIN: MICA (CI 77499), TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492, CI 77499), CARMINE (CI 75470), RED 6 LAKE (CI 15850), RED 7 LAKE (CI 15850), RED 27 LAKE (CI 45410), YELLOW 5 LAKE (CI 19140)

Package Label Section

MINT GLAZE FX

3 ml/0.10 FL OZ LIQUID CRUELTY FREE NO ANIMAL TESTING 30 PERCENT RECYCLE
PLEASE RECYCLE

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



PLEASE RECYCLE
SVP RECYCLEZ

NO ANIMAL TESTING
NON TESTÉ SUR LES
ANIMAUX

**ACTIVE INGREDIENTS/
INGRÉDIENTS ACTIFS:**
OCTINOXATE 7.5% w/w
OXYBENZONE 2.5% w/w

USES/USAGES:
SUNBURN PROTECTANT
SPF 15/FACTEUR DE
PROTECTION SOLAIRE
FPS 15 UVA/UVB
PROTECTION PROTÈGE
CONTRE LES RAYONS
UVA ET UVB.

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.
DISCONTINUE USE IF SKIN
IRRITATION DEVELOPS OR
INCREASES. IF IRRITATION
PERSISTS, CONSULT A
HEALTH CARE PRACTITIONER.
FOR EXTERNAL USE ONLY.
KEEP OUT OF REACH OF
CHILDREN.

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
RÉGULIÈRE D'ÉCRANS
SOLAIRES PEUT, AVEC
LES ANNÉES, RÉDUIRE LE
RISQUE DE CES EFFETS
NOCIFS. 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.
POUR L'USAGE EXTERNE
SEULEMENT.
TENIR HORS DE PORTÉE
DES ENFANTS.

**DIRECTIONS/
MODE D'EMPLOI:**
APPLY PRIOR TO SUN
EXPOSURE. REAPPLY AS
NEEDED OR AFTER
EATING OR DRINKING.
APPLIQUER AVANT
L'EXPOSITION AU SOLEIL.
RÉAPPLIQUEZ COMME
NÉCESSAIRE OU APRÈS
CONSUMMATION OU BOIRE.

THIS PROTECTIVE,
FORTIFYING & FRESHENING
GLAZED BALM MAINTAINS
YOUTHFUL LOOKING LIPS.
USE AS A POUT PERFECTING
PRIMER TO SOFTEN THE
APPEARANCE OF LINES AND
HYDRATE LIPS.

CE BAUME GLACÉ
PROTECTEUR, FORTIFIANT
ET RAFFRAÎCHISSANT PRÉSERVE
LA JEUNESSE DE VOS LÈVRES.
S'APPLIQUE COMME BASE
CORRECTRICE POUR
ATTÉNUER LES RIDULES ET
HYDRATER LES LÈVRES.



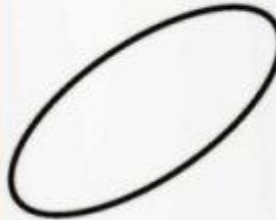
CRUELTY FREE
SANS CRUAUTÉ



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

MINT
GLAZE FX



MOISTURIZING
LIP TREAT-MINT
PRIMER

BASE DOUCEUR
HYDRATANTE
À LA MENTHE
POUR LES LÈVRES
SPF 15 FPS
DIN 02321688

3 mL/0.10 FL OZ e
LIQUID/LIQUIDE

**INACTIVE INGREDIENTS/
INGRÉDIENTS INACTIFS:**
HYDROGENATED POLYISO-
BUTENE, POLYGLYCERYL-2
TRISOSTEARATE, TRIDECYL
TRIMELLITATE, CYCLOPEN-
TASILOXANE, POLYETHY-
LENE, C10-30 CHOLESTER-
OL/LANOSTEROL ESTERS,
BUTYROSPERMIUM PARKII
(SHEA BUTTER), DIPALMI-
TOYL HYDROXYPROLINE,
MENTHA PIPERITA
(PEPPERMINT),
ETHYLHEXYL PALMITATE,
TOCOPHERYL ACETATE,
CHOLESTERYL HYDROXY-
STEARATE, TETRAHEXYL-
DECYL ASCORBATE,
LINOLEIC ACID, LINOLENIC
ACID, TRIBEHENIN,
SORBITAN ISOSTEARATE,
SILICA DIMETHYL SILYLATE,
BUTYLENE GLYCOL,
CAPRYLYL GLYCOL,
PHENOXYETHANOL,
HEXYLENE GLYCOL, SODIUM
HYALURONATE, PALMITOYL
OLIGOPEPTIDE, SILICA,
TIN OXIDE

**MAY CONTAIN/
PEUT CONTENIR:**
MICA (CI 77019), TITANIUM
DIOXIDE (CI 77891), IRON
OXIDES (CI 77491, CI 77492,
CI 77499), CARMINE
(CI 75470), RED 6 LAKE
(CI 15850), RED 7 LAKE
(CI 15850), RED 27 LAKE
(CI 45410), YELLOW 5 LAKE
(CI 19140)

MINT GLAZE FX

octinoxate, oxybenzone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68327-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7L0Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHOLESTERYL HYDROXYSTEARATE (UNII: O6K1LG6N4D)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LINOLENIC ACID (UNII: 0RBV727H71)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
COCHINEAL (UNII: TZ8Z31B35M)	
D&C RED NO. 6 (UNII: 481744AI4O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68327-004-01	3 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/09/2010	

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

Revised: 2/2013

Cover FX Skin Care, Inc.