# COVER FX TOTAL COVER FOUNDATION SPF 30- octocrylene, octis alate, avobenzone 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:** 

OCTOCRYLENE 8.5% W/W, OCTISALATE 5.0% W/W, AVOBENZONE 3.0% W/W

### Purpose/USES

**SUNSCREEN** 

# Keep out of reach of children

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

#### **USES**

HELPS PREVENT, OR PROTECTS FROM SUNBURN. SUNBURN PROTECTANT SPF 30 IF USED AS DIRECTED WITH OTHER SUN PROTECTION METHODS (SEE DIRECTIONS). DECREASES THE RISK OF SKIN CANCER AND EARLY SKIN AGING CAUSED BY THE SUN.

#### WARNINGS

WARNINGS: FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. STOP USE AND ASK A DOCTOR IF RASH OCCURS. WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. 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. AVOID CONTACT WITH EYES.

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

#### **DIRECTIONS**

APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.

SUN PROTECTION MEASURES; SPENDING TIME IN THE SUN INCREASES YOUR RISK OF

SKIN CANCER AND EARLY SKIN AGING. TO DECREASE THIS RISK, REGULARLY USE A SUNSCREEN WITH A BROAD SPECTRUM SPF VALUE OF 15 OR HIGHER AND OTHER PROTECTION MEASURES INCLUDING:

- LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 A.M. 2 P.M.
- WEAR LONG SLEEVED SHIRTS, PANTS, HATS, AND SUNGLASSES

#### OTHER INFORMATION

ANTIOXIDANT INFUSED FULL COVERAGE FOUNDATION AND CONCEALER IN ONE WITH BROAD SPECTRUM SPF 30 PROTECTION. GIVES AN ALL-DAY SATIN FINISH THAT NOURISHES AND PROTECTS WITH ANTI-AGING BENEFITS. CLINICALLY TESTED. PARABEN, FRAGRANCE, GLUTEN, MINERAL OIL AND TALC FREE.

OTHER INFORMATION: PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

#### **INACTIVE INGREDIENTS**

BISABOLOL, C12-15 ALKYL BENZOATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CERAMIDE 2, CHROMIUM OXIDE BREENS (CL 77288), COPERNICIA CERIFERA (CARNAUBA) WAX, DEHYDROACETIC ACID, DIISOSTEARYL MALATE, ETHYL LINOLEATE, ETHYL LINOLENATE, ETHYL OLEATE, HYDROGENATEDD POLYISOBUTENE, IRON OXIDES (CL 77491, CL 77499, CL 77499), NEOPENTYL GLYCOL DICAPRATE, PALMITOYL OLIGOPEPTIDE, PEG-10 RAPESEED STEROL, PHYTOSPHINGOSINE, POLYGLYCERL-2 TRIISOSSTEARATE, SILICA, SQUALANE, SYNTHETIC BEESWAX, TETRAHEXYLDECYL ASCORBATE, TOCOPHEROL, TRICONTANYL PVP, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE, TRIS (PPG-3 BENTZYL ETHER) CITRATE, TITANIUM DIOXIDE (CL 77891)

### PRODUCT LABEL

COVER 1 FX

TOTAL COVER CREAM FOUNDATION

**BROAD SPECTRUM** 

**SPF 30** 

NET WT/ 10G/0.35 OZ e

**CRUELTY FREE** 

DIST. BY COVER FX SKIN CARE INC.

TORONTO, ONTARIO CANADA M3J 2W8. LONDON W1V 2LD

MADE IN CANADA WWW.COVERFX.COM



## **COVER FX TOTAL COVER FOUNDATION SPF 30**

octocrylene, octisalate, avobenzone cream

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68327-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8.5 mg in 1 g	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mg in 1 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
LEVOMENOL (UNII: 24WE03BX2T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERAMIDE 2 (UNII: C04977SRJ5)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
<b>DEHYDRO ACETIC ACID</b> (UNII: 2KAG279 R6 R)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)	
ETHYL LINOLENATE (UNII: T54Y8 H0 42V)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
HYDRO GENATED POLYBUTENE (370 MW) (UNII: V5H8103878)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
PEG-10 RAPESEED STEROL (UNII: 258 O 76 T85M)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SQUALANE (UNII: GW89575KF9)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TOCOPHEROL (UNII: R0 ZB2556 P8)	
TRICONTANYL POVIDONE (4 TRICONTANYL BRANCHES/REPEAT) (UNII: N0 SS3Q238D)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68327-010-01	10 g in 1 CASE		
2 NDC:68327-010-03	1.5 g in 1 PACKET		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2012	

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

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

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