

TINTED MOISTURIZER SPF-15- octinoxate, octisalate and titanium dioxide cream
Femme Couture International, Inc

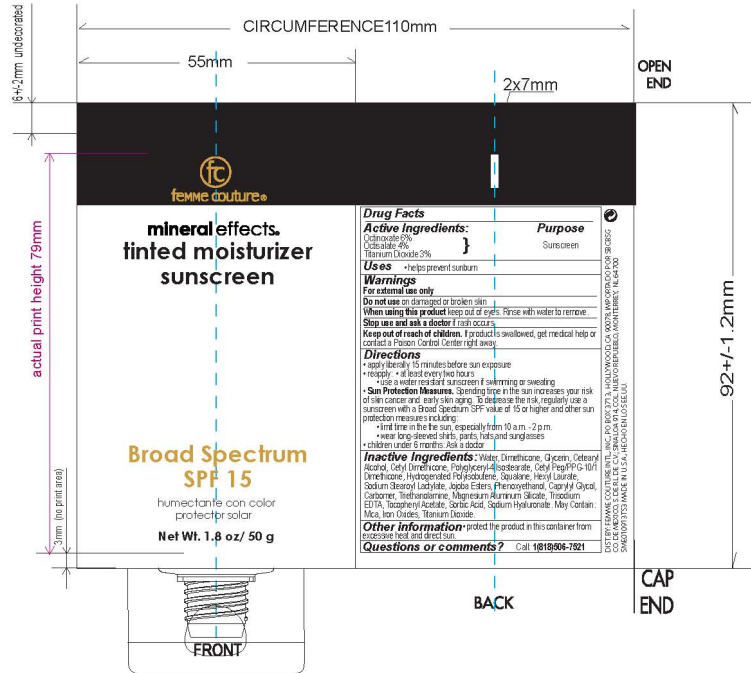
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Octinoxate 6%
Octisalate 4%
Titanium Dioxide 3%

Sunscreen

For external use only
Do not use on damaged or broken skin
When using this product keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

PROGRAM/DESCRIPTION: FCTINTED MOISTURIZER SPF 15 SUNSCREEN DECO	
FILE NAME: FCTINTED MOISTURIZER SPF 15 SUNSCREEN DECO.ai	DATE: 8.9.11
SIZE: 35mm tube	SPECIAL INSTRUCTIONS:
COLORS: ■ OPAQUE BLACK ■ hot stamp gold	



a21b2c1b-2116-4fd6-b254-29f4bf1ec23f

TINTED MOISTURIZER SPF-15

octinoxate, octisalate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76351-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	3.06 g in 51.03 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.04 g in 51.03 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	1.53 g in 51.03 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Carbomer 934 (UNII: Z135WT9208)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
Glycerin (UNII: PDC6A3C0OX)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
Dimethicone (UNII: 92RU3N3Y1O)	
Dimethicone (UNII: 92RU3N3Y1O)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sorbic Acid (UNII: X045WJ989B)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Dimethicone (UNII: 92RU3N3Y1O)	
HYDROGENATED POLYBUTENE (370 MW) (UNII: V5H8103878)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
Squalane (UNII: GW89575KF9)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
Trolamine (UNII: 9O3K93S3TK)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
Mica (UNII: V8A1AW0880)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76351-100-01	51.03 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/26/2011	

Labeler - Femme Couture International, Inc (010053513)

Establishment

Name	Address	ID/FEI	Business Operations
Nuworld Corporation		628045858	manufacture, pack, label

Establishment			
Name	Address	ID/FEI	Business Operations
Nu-World Corporation		968288055	label, pack

Revised: 6/2011

Femme Couture International, Inc