

SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA COSMETICS-

octinoxate, octisalate, oxybenzone cream

Jafra Cosmetics 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.

Skin Defense Concealer Broad Spectrum SPF 15

Active Ingredients	Purpose
Octinoxate 7%	Sunscreen
Octisalate 3%	Sunscreen
Oxybenzone 2%	Sunscreen

Uses

helps prevent sunburn

if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings

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.

Directions

Apply liberally 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

Children under 6 months: Ask a doctor

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 broad spectrum SPF of 15 or higher and other sun protection measures including:

limit time in the sun, especially from 10 a.m. - 2 p.m.

wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Butylene Glycol, Glyceryl Stearate, Stearic Acid, Isopropyl Isostearate, Di-PPG-3 Myristyl Ether Adipate, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Cetyl Alcohol, Triethanolamine, Lecithin, Silica, Dimethicone, Polysorbate 20, Hydrolyzed Lupinus Albus (Lupine) Protein, Medicago Sativa (Alfalfa) Seed Extract, DMDM Hydantoin, Xanthan Gum, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Magnesium Aluminum Silicate, Tocopheryl Acetate, Tagetes Erecta (African Marigold) Extract, Ipomoea Batatas Tuber Extract, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA [May Contain +/- : Titanium Dioxide/CI 77891, Iron Oxides/CI 77491/CI 77492/CI 77499]

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15 ml .5 Fl Oz (US)

Drug Facts

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Octinoxate 7%.....	Sunscreen
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Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours ■ children under 6 months: Ask a doctor
- **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 sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Butylene Glycol, Glyceryl Stearate, Stearic Acid, Isopropyl Isostearate, Di-PPG-3 Myristyl Ether Adipate, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Cetyl Alcohol, Triethanolamine, Lecithin, Silica, Dimethicone, Polysorbate 20, Hydrolyzed Lupinus Albus (Lupine) Protein, Medicago Sativa (Alfalfa) Seed Extract, DMDM Hydantoin, Xanthan Gum, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Magnesium Aluminum Silicate, Tocopheryl Acetate, Tagetes Erecta (African

Drug Facts (continued)

Inactive ingredients (continued)

Marigold) Extract, Ipomoea Batatas Tuber Extract, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA [May Contain +/- : Titanium Dioxide/CI 77891, Iron Oxides/CI 77491/CI 77492/CI 77499]

Other information ■ protect this product from excessive heat and direct sun



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octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
STEARIC ACID (UNII: 4ELV7Z65AP)
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)
CETYL ALCOHOL (UNII: 936JST6JCN)
TROLAMINE (UNII: 9O3K93S3TK)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
ALFALFA (UNII: DJO934BRBD)
DMDM HYDANTOIN (UNII: BYR0546TOW)
XANTHAN GUM (UNII: TTV12P4NEE)
CHONDRUS CRISPUS (UNII: OQS23HUA1X)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SWEET POTATO (UNII: M9WGG9Z9GK)
PEG-4 LAURATE (UNII: AYP4VM3N1Z)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
EDETATE TRISODIUM (UNII: 420IP921MB)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-117-02	1 in 1 PACKAGE	05/22/2013	
1	NDC:68828-117-01	30 mL in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/22/2013	

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-117)

