

**LIGHT SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA-  
octinoxate, octisalate, oxybenzone cream**  
**MEDIUM SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA-  
octinoxate, octisalate, oxybenzone cream**  
**DARK SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA-  
octinoxate, octisalate, oxybenzone cream**  
**Jafra Cosmetics International Inc**

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**Skin Defense Concealer 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]

51 mm

## Drug Facts

<b>Active ingredients</b>	<b>Purpose</b>
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

**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.

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

**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

51 mm

**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

51 mm





## LIGHT SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA

octinoxate, octisalate, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-170
<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	7 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>ISOPROPYL ISOSTEARATE</b> (UNII: C67IXB9Y7T)
<b>DI-PPG-3 MYRISTYL ETHER ADIPATE</b> (UNII: T32481VTXW)
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)
<b>HYDROGENATED PALM GLYCERIDES</b> (UNII: YCZ8EM144Q)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>ALFALFA SEED</b> (UNII: 67PHZ58858)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>CHONDRUS CRISPUS</b> (UNII: OQS23HUA1X)
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>SWEET POTATO</b> (UNII: M9WGG9Z9GK)
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-170-02	1 in 1 CARTON	05/22/2013	12/31/2023
1	NDC:68828-170-01	15 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/22/2013	12/31/2023

## MEDIUM SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA

octinoxate, octisalate, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-171
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0K00R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ISOPROPYL ISOSTEARATE</b> (UNII: C67IXB9Y7T)	
<b>DI-PPG-3 MYRISTYL ETHER ADIPATE</b> (UNII: T32481VTXW)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>HYDROGENATED PALM GLYCERIDES</b> (UNII: YCZ8EM144Q)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>ALFALFA SEED</b> (UNII: 67PHZ58858)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CHONDRUS CRISPUS</b> (UNII: OQS23HUA1X)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SWEET POTATO</b> (UNII: M9WGG9Z9GK)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68828-171-02	1 in 1 CARTON	05/22/2013	12/31/2023
1	NDC:68828-171-01	15 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/22/2013	12/31/2023

## DARK SKIN DEFENSE CONCEALER BROAD SPECTRUM SPF 15 JAFRA

octinoxate, octisalate, oxybenzone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-172
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ISOPROPYL ISOSTEARATE</b> (UNII: C67IXB9Y7T)	
<b>DI-PPG-3 MYRISTYL ETHER ADIPATE</b> (UNII: T32481VTXW)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>HYDROGENATED PALM GLYCERIDES</b> (UNII: YCZ8EM144Q)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>ALFALFA SEED</b> (UNII: 67PHZ58858)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CHONDRUS CRISPUS</b> (UNII: OQS23HUA1X)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SWEET POTATO</b> (UNII: M9WGG9Z9GK)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-172-02	1 in 1 CARTON	05/22/2013	06/01/2019
1	NDC:68828-172-01	15 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/22/2013	

**Labeler** - Jafra Cosmetics International Inc (041676479)

**Registrant** - Jafra Cosmetics International Inc (041676479)

### Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-170, 68828-171, 68828-172)

Revised: 1/2024

Jafra Cosmetics International Inc