

**LONG WEAR MAKEUP BROAD SPECTRUM SPF 20 BRONZE JAFRA- octisalate, zinc oxide cream**

**JAFRA COSMETICS INTERNATIONAL**

*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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**Long Wear Makeup Broad Spectrum SPF 20 Bronze**

**Active**

**Ingredients      Purpose**

Octisalate 3% ..... Sunscreen

Zinc Oxide 6.8% .... 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
- 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 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

Water/Aqua, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Phenyl Trimethicone, C12-15 Alkyl Benzoate, Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Phenyl Dimethicone, Di-PPG-3 Myristyl Ether Adipate, Caprylyl Methicone, PEG-10 Dimethicone, Distearidimonium Hectorite, Propanediol, Sodium Chloride, Squalane, Boron Nitride, Synthetic Fluorophlogopite, Aloe Barbadensis Leaf Juice, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Sodium Hyaluronate, Butylene Glycol, Glycyrrhiza Glabra (Licorice) Extract, Benzimidazole Diamond Amidoethyl Urea Carbamoyl Propyl Polymehtylsilsesquioxane, Lentinus Edodes (shiitake) Extract, Ipomoea Batatas Tuber Extract, Centella Asiatica Extract, Withania Somniferia Extract, Butylene Glycol, Biosaccharide Gum-4, Smithsonite Extact, Chondrus Crispus (Carrageenan) Extract, Triethoxycaprylylsilane [May Containt +/-: Titanium

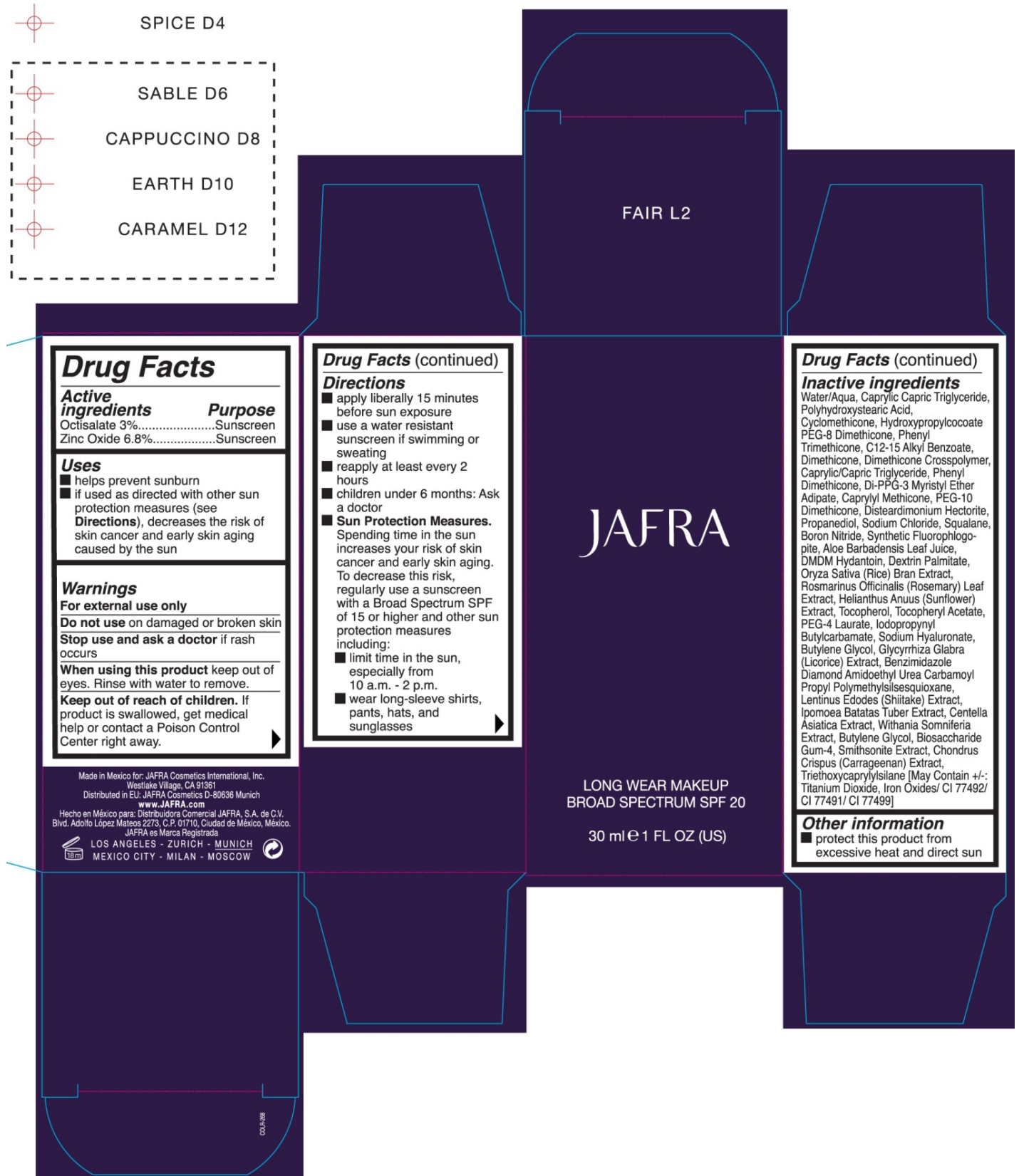
Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

JAFRA

Long Wear Makeup

Broad Spectrum SPF 20

30 ml / 1 FL oz (us)



SPICE D4

SABLE D6

CAPPUCCINO D8

EARTH D10

CARAMEL D12

FAIR L2

### Drug Facts

| Active ingredients   | Purpose   |
|----------------------|-----------|
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| Zinc Oxide 6.8%..... | Sunscreen |

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### Drug Facts (continued)

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### Drug Facts (continued)

**Inactive ingredients**

Water/Aqua, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Phenyl Trimethicone, C12-15 Alkyl Benzoate, Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Phenyl Dimethicone, Di-PPG-3 Myristyl Ether Adipate, Caprylyl Methicone, PEG-10 Dimethicone, Distearidimonium Hectorite, Propanediol, Sodium Chloride, Squalane, Boron Nitride, Synthetic Fluorophlogopite, Aloe Barbadensis Leaf Juice, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Sodium Hyaluronate, Butylene Glycol, Glycyrrhiza Glabra (Licorice) Extract, Benzimidazole Diamond Amidoethyl Urea Carbamoyl Propyl Polymethylsilsesquioxane, Lentinus Edodes (Shiitake) Extract, Ipomoea Batatas Tuber Extract, Centella Asiatica Extract, Withania Somniferia Extract, Butylene Glycol, Biosaccharide Gum-4, Smithsonite Extract, Chondrus Crispus (Carrageenan) Extract, Triethoxycaprylylsilane [May Contain +/- Titanium Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

LONG WEAR MAKEUP  
BROAD SPECTRUM SPF 20

30 ml e 1 FL OZ (US)

### Other information

protect this product from excessive heat and direct sun

Made in Mexico for: JAFRA Cosmetics International, Inc.  
Westlake Village, CA 91361  
Distributed in EU: JAFRA Cosmetics D-90636 Munich  
[www.JAFRA.com](http://www.JAFRA.com)

Hecho en México para: Distribuidora Comercial JAFRA, S.A. de C.V.  
Blvd. Adolfo López Mateos 2273, C.P. 01710, Ciudad de México, México.  
JAFRA es Marca Registrada

LOS ANGELES - ZURICH - MUNICH  
MEXICO CITY - MILAN - MOSCOW

COLL 938

# LONG WEAR MAKEUP BROAD SPECTRUM SPF 20 BRONZE JAFRA

octisalate, zinc oxide cream

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-265 |
| Route of Administration | TOPICAL        |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)  | OCTISALATE        | 3 g in 100 mL   |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION       | 6.8 g in 100 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R)   |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)  |          |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)                                   |          |
| CYCLOMETHICONE (UNII: NMQ347994Z)  |          |
| HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)                              |          |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)   |          |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)   |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)   |          |
| DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) |          |
| DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)                                     |          |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)  |          |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)  |          |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)   |          |
| PROPANEDIOL (UNII: 5965N8W85T)   |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)   |          |
| SQUALANE (UNII: GW89575KF9)  |          |
| BORON NITRIDE (UNII: 2U4T60A6YD)   |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)  |          |
| DMDM HYDANTOIN (UNII: BYR0546TOW)  |          |
| DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)                                  |          |
| RICE BRAN (UNII: R60QEP13IC)   |          |
| ROSEMARY (UNII: IJ67X351P9)  |          |
| HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)                                     |          |
| TOCOPHEROL (UNII: R0ZB2556P8)  |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)  |          |
| PEG-4 LAURATE (UNII: AYP4VM3N1Z)   |          |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)   |          |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH)  |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)   |          |
| LICORICE (UNII: 61ZBX54883)  |          |
| LENTINULA EDODES MYCELIUM (UNII: CU2S39TB8O)   |          |
| SWEET POTATO (UNII: M9WGG9Z9GK)  |          |

|   |  |
|---|--|
| CENTELLA ASIATICA (UNII: 7M867G6T1U)            |  |
| WITHANIA SOMNIFERA LEAF (UNII: J337CNM3CW)      |  |
| BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)         |  |
| CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78) |  |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)      |  |

### Other Ingredients

| Ingredient Kind | Ingredient Name                         | Quantity |
|-----------------|---|----------|
| May contain     | TITANIUM DIOXIDE (UNII: 15FIX9V2JP)     |          |
| May contain     | FERRIC OXIDE YELLOW (UNII: EX438O2MRT)  |          |
| May contain     | FERRIC OXIDE RED (UNII: 1K09F3G675)     |          |
| May contain     | FERROSO FERRIC OXIDE (UNII: XM0M87F357) |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68828-265-02 | 1 in 1 BOX   | 02/21/2017           |                    |
| 1 | NDC:68828-265-01 | 30 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 final | part352                                  | 02/21/2017           |                    |

**Labeler** - JAFRA COSMETICS INTERNATIONAL (041676479)

**Registrant** - JAFRA COSMETICS INTERNATIONAL (041676479)

### Establishment

| Name                             | Address | ID/FEI    | Business Operations    |
|----------------------------------|---------|-----------|------------------------|
| Jafra Manufacturing, S.A. de C.V |         | 814732061 | manufacture(68828-265) |

Revised: 2/2019

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