

**CARAMEL LONG WEAR MAKEUP BROAD SPECTRUM SPF 20- 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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**Caramel - Long Wear Makeup Broad Spectrum SPF 20**

**Active**

**Ingredients      Purpose**

Octisalate 3% ..... Sunscreen

Zinc Oxide 6.82% .... 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, Triethoxycaprylylsilane, 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, Dimethicone, 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 Polymethylsiloxane, Lentinus Edodes (shiitake) Extract, Ipomoea Batatas Tuber Extract, Centella Asiatica Extract, Withania Somnifera Extract, Butylene Glycol, Biosaccharide Gum-4, Smithsonite Extract, Chondrus Crispus (Carrageenan) Extract [ May

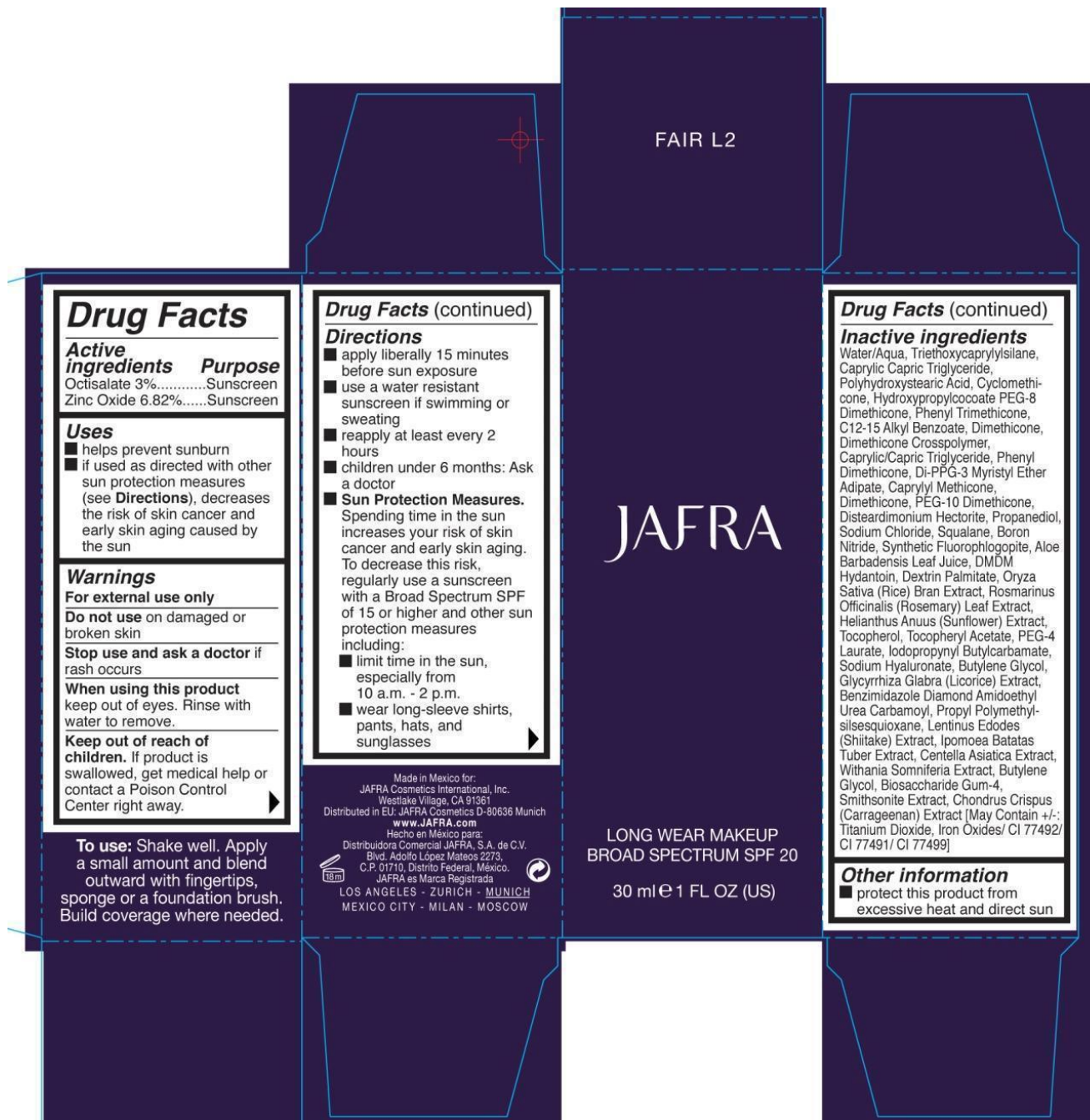
Containt +/-: Titanium Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

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Caramel Long Wear Makeup

Broad Spectrum SPF 20

30 ml / 1 FL oz (us)



## CARAMEL LONG WEAR MAKEUP BROAD SPECTRUM SPF 20

octisalate, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-335
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SO2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	6.82 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE</b> (UNII: 8TE0BZU36S)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DI-PPG-3 MYRISTYL ETHER ADIPATE</b> (UNII: T32481VTXW)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>ICODextrin</b> (UNII: 2NX48Z0A9G)	
<b>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>LENTINULA EDODES MYCELIUM</b> (UNII: CU2S39TB8O)	
<b>SWEET POTATO</b> (UNII: M9WGG9Z9GK)	
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)	
<b>BIO SACCCHARIDE GUM-4</b> (UNII: 9XRL057X90)	
<b>CHONDRUS CRISPUS CARRAGEENAN</b> (UNII: UE856F2T78)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-335-02	1 in 1 BOX	07/07/2015	
1	NDC:68828-335-01	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	07/07/2015	

**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(68828-335)

Revised: 6/2020

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