

SABLE 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.

Sable - Long Wear Makeup Broad Spectrum SPF 20

Active

Ingredients Purpose

Octisalate 3% Sunscreen

Zinc Oxide 6.82% Sunscree

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

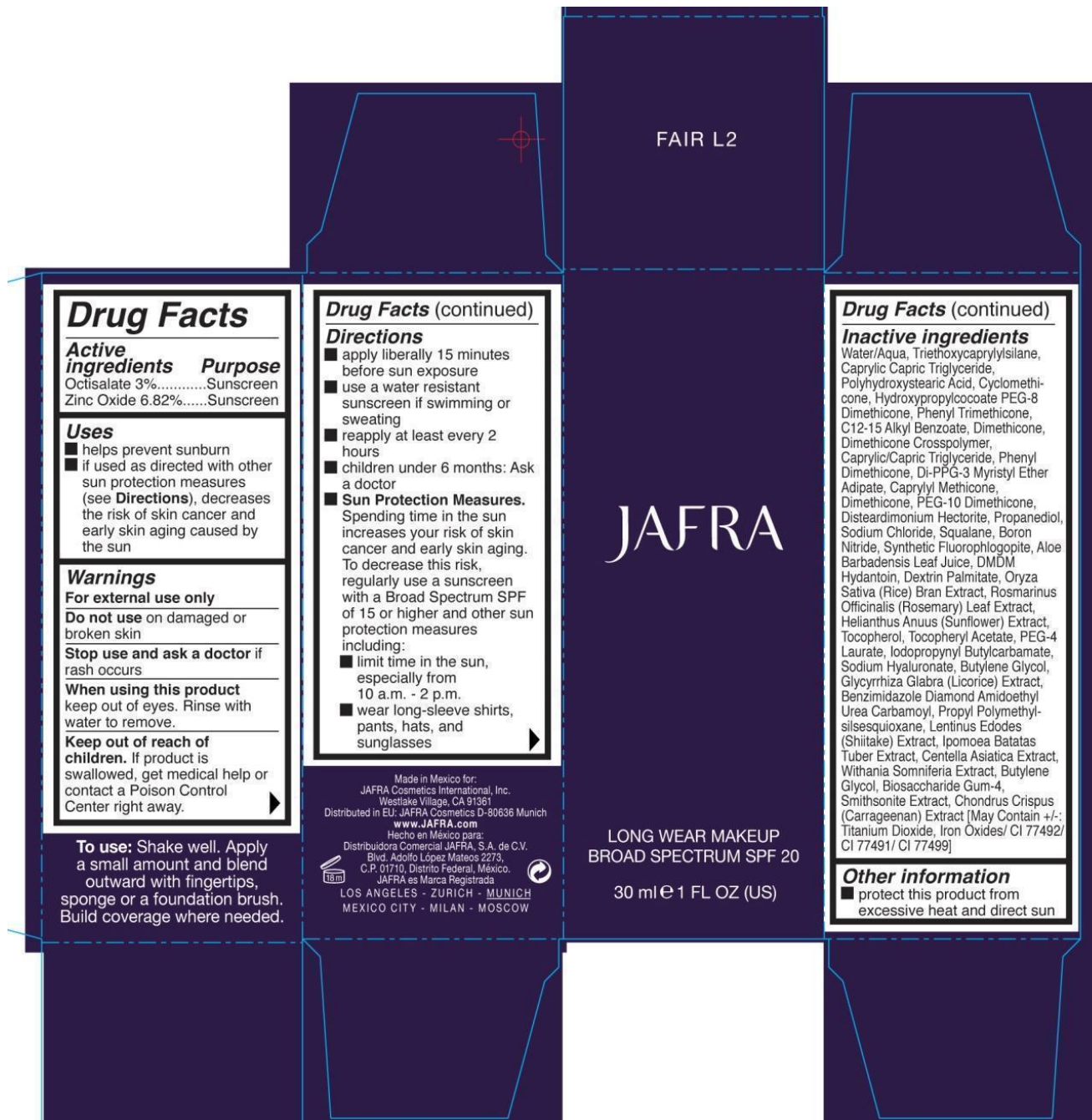
Water/Aqua, Triethoxycaprylylsilane, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Phenyl Trimethicone, C12-15 Alkyl Benzoate, Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Phenyl Dimethicone, Di-PPG-3 Myristyl Ether Adipate, Caprylyl Methicone, Dimethicone, PEG-10 Dimethicone, Disteardimonium 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 [May Containt +/-: Titanium Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

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Long Wear Makeup

Broad Spectrum SPF 20

30 ml / 1 FL oz (us)



SABLE LONG WEAR MAKEUP BROAD SPECTRUM SPF 20

octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-337
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	6.82 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
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)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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)	
ICODextrin (UNII: 2NX48Z0A9G)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
LENTINULA EDODES MYCELIUM (UNII: CU2S39TB8O)	
SWEET POTATO (UNII: M9WGG9Z9GK)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-337-02	1 in 1 BOX	07/07/2015	
1	NDC:68828-337-01	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(68828-337)

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