

SKIN BALANCING MAKEUP BROAD SPECTRUM SPF 20 JAFRA- avobenzone, octinoxate, octisalate, octocrylene cream

Jafra Cosmetics

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 Balancing Makeup Broad Spectrum SPF 20

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Octinoxate 6%	Sunscreen
Octisalate 4%	Sunscreen
Octocrylene 2.7%	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.

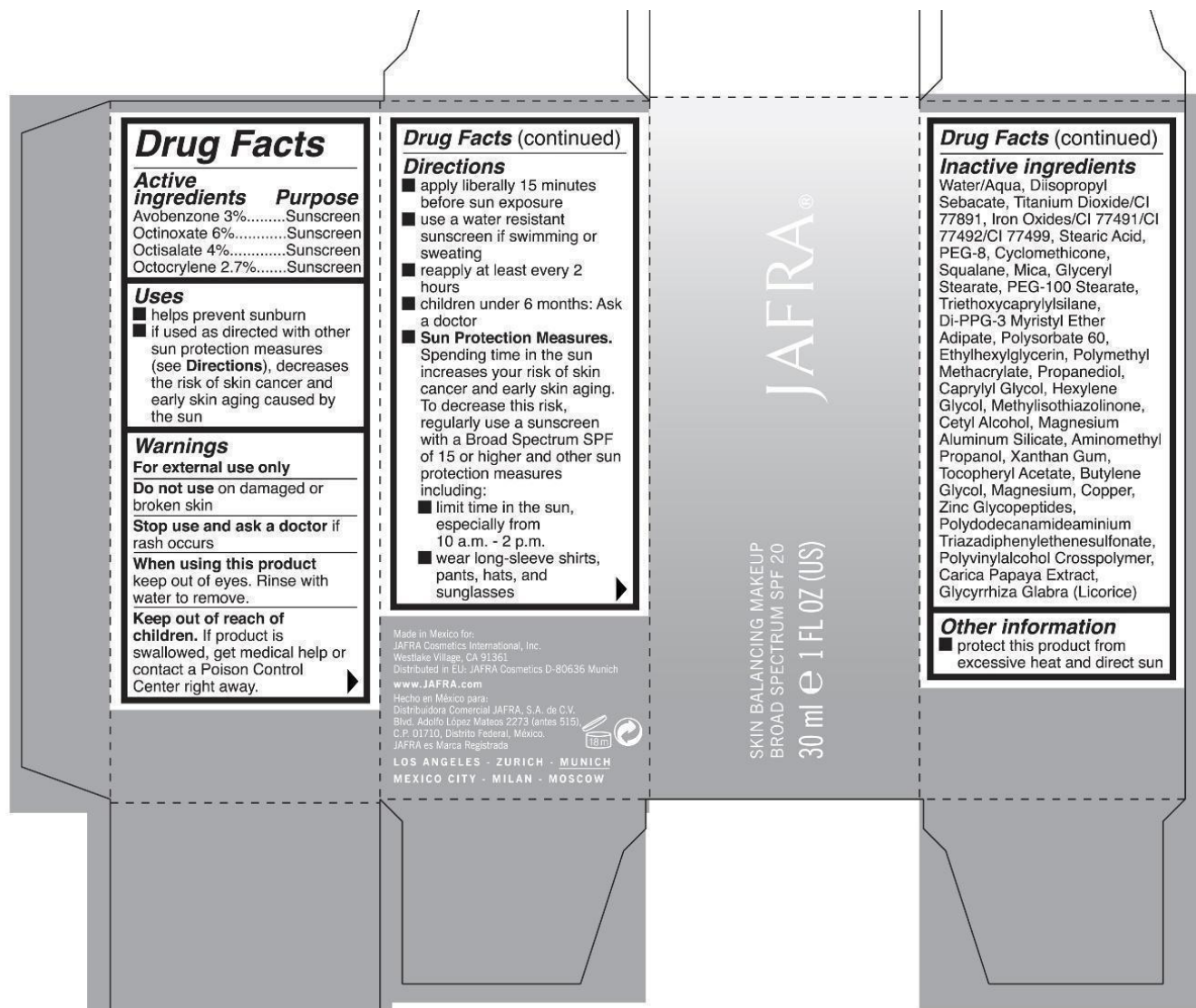
wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Diisopropyl Sebacate, Titanium Dioxide/CI 77891, Iron Oxides/CI 77491/CI77492/CI 77499, Stearic Acid, PEG-8, Cyclomethicone, Squalane, Mica, Glyceryl Stearate, PEG-100 Stearate, Triethoxycaprylylsilane, Di-PPG-3 Myristyl Ether Adipate, Polysorbate 60, Ethylhexylglycerin, Polymethyl Methacrylate, Proanediol, Caprylyl Glycol, Hexylene Glycol, Methylisothiazolinone, Cetyl Alcohol, Magnesium Aluminum Silicate, Aminomethyl Propanol, Xanthan Gum, Tocopheryl Acetate,

Butylene Glycol, Magnesium, Copper, Zinc Glycopeptides, Polydodecanamideaminium Triazadiphenylethanesulfonate, Polyvinylalcohol Crosspolymer, Carica papaya Extract, Glycyrrhiza Glabra (Licorice)

Skin Balancing Makeup
Broad Spectrum SPF 20
30 ml 1 FL OZ



SKIN BALANCING MAKEUP BROAD SPECTRUM SPF 20 JAFRA

avobenzone, octinoxate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-194
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
SQUALANE (UNII: GW89575KF9)	
MICA (UNII: V8A1AW0880)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MAGNESIUM (UNII: I38ZP9992A)	
COPPER (UNII: 789U1901C5)	
PAPAYA (UNII: KU94FIY6JB)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	

Product Characteristics

Color	brown (Fair) , brown (Nude) , brown (Bare) , brown (Natural Tan) , brown (Tawny) , brown (Honey) , brown (Bronze) , brown (Spice)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-194-02	1 in 1 CARTON	08/01/2014	
1	NDC:68828-194-01	30 mL in 1 BOTTLE; 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	08/01/2014	

Labeler - Jafra Cosmetics (041676479)

Registrant - Jafra Cosmetics (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra manufacturing		814732061	manufacture(68828-194)

Revised: 6/2019

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