#### SOFT BEIGE ALWAYS COLOR STAY-ON MAKEUP BROAD SPECTRUM SPF 15 JAFRAoctinoxate, oxybenzone, titanium dioxide liquid 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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#### Soft Beige alway color stay on makeup SPF 15

Active Ingredients Purpose

Octinoxate 5% Sunscreen

Oxybenzone 2% Sunscreen

Titanium Dioxide 2.1% 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.

Stop use and ask a doctor if rash occurs

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 skin aging. to decrease

this risk, regularly use a sunscreen with a Broad Spectrum SPF

value of 15 or higher and other sun measures including;

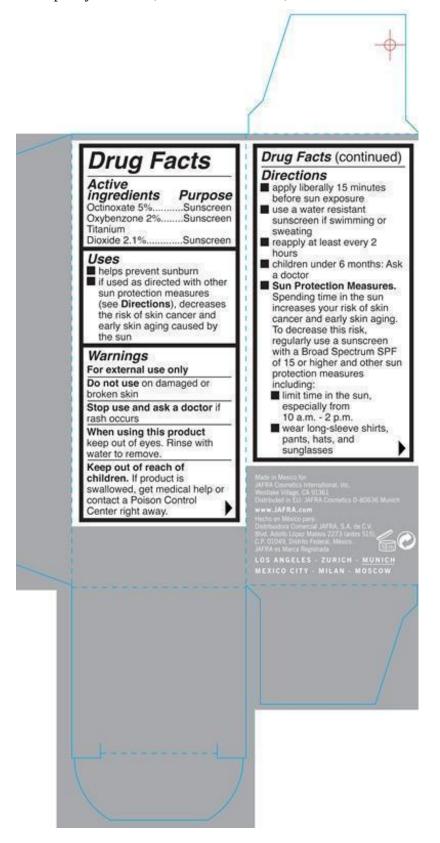
limit time in the sun, especially from 10 a.m. - 2 p.m.

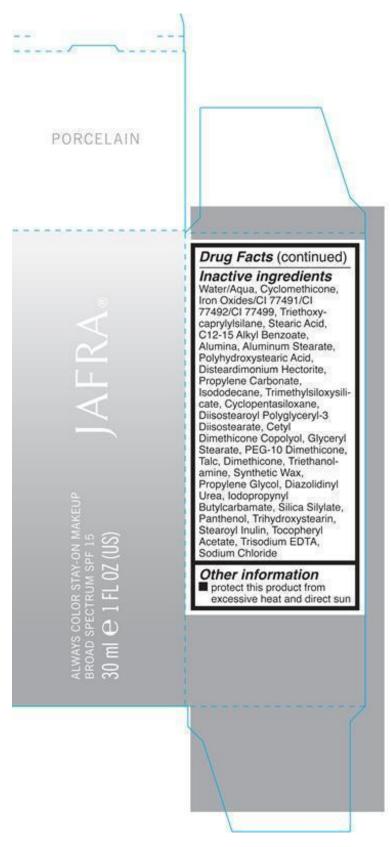
wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Cyclomethicone, Iron Oxides/CI 77491/77492/77499, Triethoxycaprylysilane, Stearic Acid, C12-15 Alkyl Benzoate, Alumina, Aluminum Stearate, Polyhydroxystearic Acid, Disteardimonium Hectorite, Propylene Carbonate, Isododecane, Trimethylsiloxysilicate, cyclopentasiloxane, Diisostearyl Polyglyceryl-3 Diisostearate, Cetyl Dimethicone Colpolyol, Glyceryl Stearate, PEG-10

Dimethicone, Talc, Dimethicone, Triethanolamine, Synthetic Wax, Propylene Glycol, Diazolidnyl Urea, Iodopropynyl Butylcarbamate, Silica Silylate, Panthenol, Trihydroxystearin, Stearoyl Inulin, Tocopheryl Acetate, Trisodium EDTA, Sodium Chloride.





Jafra
Soft Beige Always Color Stay-on Makeup
Broad Spectrum SPF 15
30 ml 1 Fl Oz

## 15 JAFRA

octinoxate, oxybenzone, titanium dioxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.1 g in 100 mL	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM STEARATE (UNII: U6 XF9 NP8 HM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ISODODECANE (UNII: A8289P68Y2)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8 PR7V1SVM0)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
<b>SYNTHETIC WAX (1800 MW)</b> (UNII: 248P1AUJ90)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PANTHENOL (UNII: WV9CM0O67Z)	
TRIHYDRO XYSTEARIN (UNII: 06 YD7896S3)	
ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE TRISODIUM (UNII: 420 IP9 21MB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-126- 02	1 in 1 CARTON	0 3/0 1/20 13	
1	NDC:68828-126- 01	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 3/0 1/20 13		

# 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(68828-126)	

Revised: 1/2019 JAFRA COSMETICS INTERNATIONAL