

## **WARM HONEY ALWAYS COLOR STAY-ON MAKEUP BROAD SPECTRUM SPF**

**15 JAFRA- octinoxate, oxybenzone, titanium dioxide 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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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.

### 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

Water/Aqua, Cyclomethicone, Iron Oxides/CI 77491/77492/77499, Triethoxycaprylsilane, Stearic Acid, C12-15 Alkyl Benzoate, Alumina, Aluminum Stearate, Polyhydroxystearic Acid, Distearidmonium Hectorite, Propylene Carbonate, Isododecane, Trimethylsiloxysilicate, cyclopentasiloxane, Diisostearyl Polyglyceryl-3 Diisostearate, Cetyl Dimethicone Copolyol, Glyceryl Stearate, PEG-10 Dimethicone, Talc, Dimethicone, Triethanolamine, Synthetic Wax, Propylene Glycol, Diazolidnyl Urea, Iodopropynyl Butylcarbamate, Silica Silylate, Panthenol, Trihydroxystearin, odium Chloride, Stearoyl Inulin, Trisodium EDTA, Tcopheryl Acetate.

# Drug Facts

## Active ingredients Purpose

Octinoxate 5%.....Sunscreen  
Oxybenzone 2%.....Sunscreen  
Titanium  
Dioxide 2.29%.....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

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**Stop use and ask a doctor** if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

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# Drug Facts (continued)

## 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 ▶

Made in Mexico for:  
JAFRA Cosmetics International, Inc.  
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[www.JAFRA.com](http://www.JAFRA.com)

Hecho en México para:  
Distribuidora Comercial JAFRA, S.A. de C.V.  
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MEXICO CITY - MILAN - MOSCOW

JAFRA®

ALWAYS COLOR STAY-ON MAKEUP  
BROAD SPECTRUM SPF 15  
30 ml e 1 FL OZ (US)

**Drug Facts** (continued)

**Inactive ingredients**

Water/Aqua, Cyclomethicone, Iron Oxides/CI 77491/CI 77492/CI 77499, Triethoxycaprylsilane, Stearic Acid, C12-15 Alkyl Benzoate, Alumina, Aluminum Stearate, Polyhydroxystearic Acid, Disteardimonium Hectorite, Propylene Carbonate, Isododecane, Trimethylsiloxysilicate, Cyclopentasiloxane, Diisostearoyl Polyglyceryl-3 Diisostearate, Glyceryl Stearate, Cetyl Dimethicone Copolyol, Talc, Dimethicone, PEG-10 Dimethicone, Triethanolamine, Synthetic Wax, Propylene Glycol, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, Silica Silylate, Panthenol, Trihydroxystearin, Sodium Chloride, Stearoyl Inulin, Trisodium EDTA, Tocopheryl Acetate

**Other information**

- protect this product from excessive heat and direct sun

Jafra

Warm Honey Always Color stay-on makeup Broad Spectrum SPF 15

30 ml 1fl oz

## WARM HONEY ALWAYS COLOR STAY-ON MAKEUP BROAD SPECTRUM SPF 15 JAFRA

octinoxate, oxybenzone, titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-185
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.29 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>SYNTHETIC WAX (1200 MW)</b> (UNII: Q3Z4BCH099)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	

<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>TRIHYDROXYSTEARIN</b> (UNII: 06YD7896S3)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-185-02	1 in 1 CARTON	12/12/2013	
1	NDC:68828-185-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/12/2013	

**Labeler** - Jafra Cosmetics international (041676479)

**Registrant** - Jafra cosmetics international (041676479)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Jafra Manufacturing S.A. de C.V.		814732061	manufacture(68828-185)

Revised: 1/2019

Jafra Cosmetics international