

**ROYAL JELLY RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 EARTH-  
octinoxate, zinc oxide liquid  
Jafra Cosmetics International Inc**

*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 ingredient**

Octinoxate 3%, Zinc Oxide 6.8%

**Purpose**

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

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

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

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

**Keep out of reach of children.** If 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 early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value 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, Titanium Dioxide, Triethoxycaprylsilane, Caprylic Capric Triglyceride,

Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, C12-15 Alkyl Benzoate, Phenyl Dimethicone, Phenyl Trimethicone, Cyclopentasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Squalane, Di-PPG-3 Myristyl Ether Adipate Caprylyl Methicone, Dimethicone, PEG-10 Dimethicone, Distearidimonium Hectorite, Boron Nitride, Royal Jelly, Propanediol, Sodium Chloride, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Withania Somniferia (Winter Cherry) Extract, Nelumbo Nucifera (Lotus) Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Smithsonite Extract, Iron Oxides/CI 77491/CI 77492/CI 77499

## Other information

Protect this product from excessive heat and direct sun

## Product label

**Drug Facts**

**Active ingredients**      **Purpose**  
 Octinoxate 3%.....Sunscreen  
 Zinc Oxide 6.8%.....Sunscreen

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Made in Mexico for: JAFRA Cosmetics International, Inc., Westlake Village, CA 91361  
 Distributed in EU: JAFRA Cosmetics, D-80638 Munich, www.JAFRA.com  
 Hecho en México para: Distribuidora Comercial JAFRA, S.A. de C.V., Blvd. Adolfo López Mateos 2273, C.P. 04710, Ciudad de México, México.  
 JAFRA, JAFRA Royal y Advanced son marcas registradas en México; Reg US Pat & TM off

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 MEXICO CITY • MILAN • MOSCOW

**Drug Facts (continued)**

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**Drug Facts (continued)**

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octinoxate, zinc oxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-504
<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	3 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	6.8 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>WITHANIA SOMNIFERA ROOT</b> (UNII: V038D626IF)	
<b>BIOSACCHARIDE GUM-4</b> (UNII: 9XRL057X90)	
<b>CHONDRUS CRISPUS CARRAGEENAN</b> (UNII: UE856F2T78)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE</b> (UNII: 8TE0BZU36S)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>DI-PPG-3 MYRISTYL ETHER ADIPATE</b> (UNII: T32481VTXW)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	
<b>ROYAL JELLY</b> (UNII: L497I37F0C)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)	
<b>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

**Packaging**

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-504-01	1 in 1 CARTON	09/06/2022	
1		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	09/06/2022	

**Labeler** - Jafra Cosmetics International Inc (041676479)

### Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-504)

Revised: 5/2023

Jafra Cosmetics International Inc