

**RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - BARE- octinoxate, zinc oxide 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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<b>Active ingredients</b>	<b>Purpose</b>
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Octinoxate 3% .....	Sunscreen
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Zinc Oxide 6.8% .....	Sunscreen
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**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 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 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, Triethoxycaprylylsilane, 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, Distardimonium Hectorite, Boron Nitride, Royal Jelly, Propanediol, Sodium Chloride, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Annuus (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**

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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 Jelly y Advanced Skin Care son Marcas Registradas en México; Reg US Pat & TM off

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**Drug Facts (continued)**

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**Drug Facts (continued)**

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**Other information**  
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## RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - BARE

octinoxate, zinc oxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-727
<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 OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.8 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<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>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<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>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>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>WITHANIA SOMNIFERA ROOT</b> (UNII: V038D626IF)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68828-727-01	1 in 1 CARTON	01/07/2022	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part352		01/07/2022	

**Labeler** - JAFRA COSMETICS INTERNATIONAL (041676479)

**Registrant** - JAFRA COSMETICS INTERNATIONAL (041676479)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-727)

Revised: 5/2023

JAFRA COSMETICS INTERNATIONAL