

RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - HONEY- 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.

Active ingredients Purpose

Octinoxate 3% Sunscreen

Zinc Oxide 6.8% 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 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, Distearidimonium 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-80636 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 Avanceson (rosal) son Marcas Registradas en México; Reg US Pat & TM off

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Drug Facts (continued)

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Other information
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JAFRA ROYAL

RADIANCE FOUNDATION
 BROAD SPECTRUM SPF 20
 30 ml e 1 FL OZ (US)

ROYAL JELLY

RJ^x

RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - HONEY

octinoxate, zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-730
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SQUALANE (UNII: GW89575KF9)	
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
ROYAL JELLY (UNII: L497I37F0C)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TOCOPHEROL (UNII: ROZB2556P8)	
PANTHENOL (UNII: WW9CM0067Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68828-730-01	1 in 1 CARTON	01/07/2022	
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		01/07/2022	

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Registrant - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment			
Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-730)

Revised: 5/2023

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