

**RADIANCE FOUNDATION BROAD SPECTRUM SPF 20- NATURAL- 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.

Radiance Foundation Broad Spectrum SPF 20 - Natural

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 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

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 2275, C.P. 04710, Ciudad de México, México.
 JAFRA, JAFRA Royal, Jelly Advanced (m) y Jelly 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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**RADIANCE FOUNDATION
BROAD SPECTRUM SPF 20**

30 ml e 1 FL OZ (US)

ROYAL JELLY



Drug Facts (continued)

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Other information

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RADIANCE FOUNDATION BROAD SPECTRUM SPF 20- NATURAL

octinoxate, zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-731
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)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
RICE BRAN (UNII: R60QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PANTHENOL (UNII: WW9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-731-01	1 in 1 CARTON	01/10/2022	
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	01/10/2022	

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(68828-731)

Revised: 5/2023

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