

RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - TAWNY- 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.

Tawny - Radiance Foundation Broad Spectrum SPF 20

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



RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - TAWNY

octinoxate, zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-734
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			
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)				
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)				
Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:68828-734-01	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(68828-734)

Revised: 5/2023

JAFRA COSMETICS INTERNATIONAL