

HAND COMPLEX BROAD SPECTRUM SPF 15 JAFRA- avobenzone, octinoxate, octisalate, oxybenzone jelly

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.

Hand Complex Broad Spectrum SPF 15

Active Ingredients Purpose

Avobenzone 3% Sunscreen

Octinoxate 7.5% Sunscreen

Octisalate 5% Sunscreen

Oxybenzone 2% 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.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings

For external use only

Do not use on damaged or broken skin

when using this product, keep out of eyes. Rinse with water to remove.

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 sunscreen measures including:

limit time in the sun, especially from 10a.m.- 2 p.m.

wear long-sleeve shirts, pants, hats, and sunglasses

Inactive

Water/Aqua, Polyglyceryl-3 Methylglucose Distearate, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Glyceryl Stearate, Glycerin, Panthenol, Tocopheryl Acetate, Withania Somnifera (Winter Cherry) Extract, Nelumbo Nucifera (Lotus) Extract, Fragrance/Parfum, Ethylhexylglycerin, Methylisothiazolinone, Royal Jelly, Helianthus Annuus (Sunflower) Sprout Extract, Lecithin, Hydrolyzed Myrtus Communis Leaf Extract, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium

EDTA



Drug Facts

Active ingredients

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Octinoxate 7.5%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Oxybenzone 2%.....	Sunscreen

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- children under 6 months: Ask a doctor
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Drug Facts (continued)

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Other information

- protect this product from excessive heat and direct sun

JAFRA

Founded by Jan and Frank Day
SINCE 1956

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 515,
Col. Tlacopac, México, D. F., 01040



JAFRA es Marca Registrada



LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - MILAN - MOSCOW

Jafra

Royal Jelly

with/con

Cellspan Complex

Hand Complex Broad Spectrum SPF 15

Cont. Net. 75 ml 2.5 fl oz (US)

HAND COMPLEX BROAD SPECTRUM SPF 15 JAFRA

avobenzone, octinoxate, octisalate, oxybenzone jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 75 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 75 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 75 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2 g in 75 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ROYAL JELLY (UNII: L497I37F0C)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-124-02	1 in 1 CARTON	02/13/2013	
1	NDC:68828-124-01	75 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/13/2013	

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Registrant - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-124)

Revised: 4/2019

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