

DAY CARE FOR HANDS BROAD SPECTRUM SPF 15 JAFRA- avobenzone, octinoxate, octisalate, oxybenzone cream
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.

JAFRA - Day Care for Hands SPF 15

Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 4%	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 sun protection measures including:
 - limit time in the sun, especially from 10a.m. - 2p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

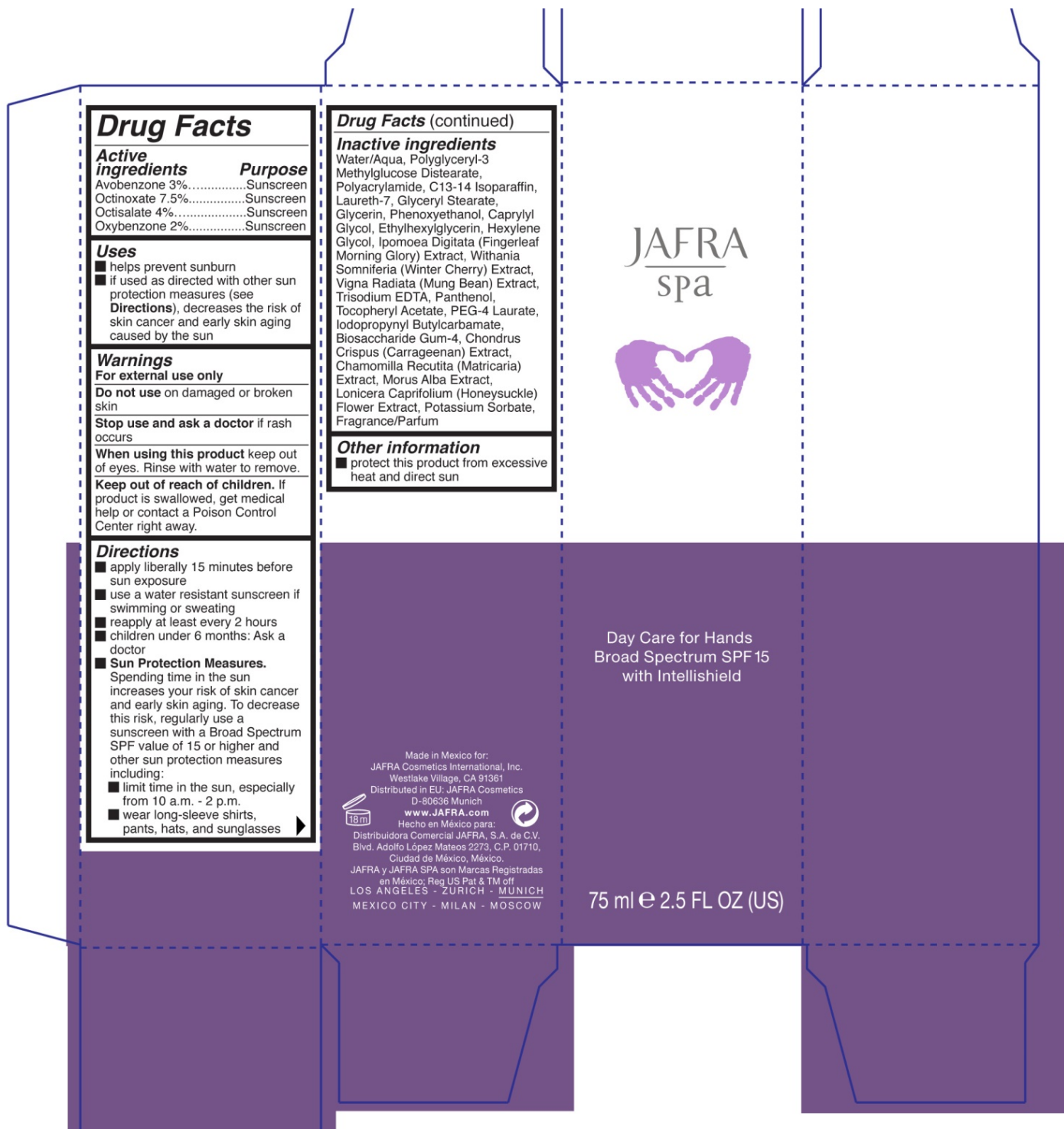
Water/Aqua, Polyglycery-3 Methylglucose Distearate, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Glyceryl Stearate, Glycerin, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Withania Somnifera (Winter Cherry) Extract, Vigna Radiata (Mung Bean) Extract, Trisodium EDTA, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Biasaccharidie Gum-4, Chondrus Crispus (Carrageenan) Extract, Chamomilla Recutita (Matricaria) Extact, Morus Alba Extract, Lonicera Caprifolium (Honeysuckle) Flower Extract, Potassium Sorbate, Fragrance/Parfum

JAFRA

spa

Day Care for Hands

Broad Spectrum SPF 15
with intellishield
75ml e 2.5 FL OZ (US)



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avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-400
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 75 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 75 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRVV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-400-02	1 in 1 BOX	06/14/2016	
1	NDC:68828-400-01	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 final	part352	06/14/2016	

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(68828-400)

Revised: 12/2018

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