HAND CARE DAY CARE BROAD SPECTRUM SPF 15 JAFRA- avobenzone, octinoxate, octis alate, oxybenzone lotion

Jafra Cosmetics International Inc

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.

Day Care Broad Spectrum 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 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 two hours

children under 6 months: Ask a doctor

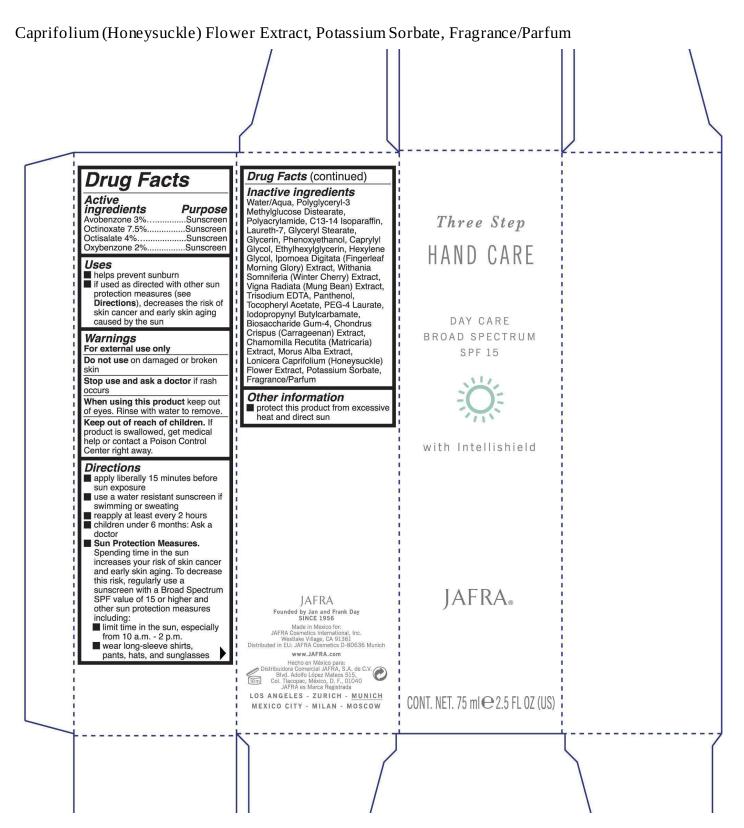
Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this 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

Water/Aqua, Polyglyceryl-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 Somniferia (Winter Cherry) Extract, Vigna Radiata (Mung Bean) Extract, Trisodium EDTA, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Chamomilla Recutita (Matricaria) Extract(MATRICARIA RECUTITA), Morus Alba Extract, Lonicera



Three Step Hand Care

Day Care Broad Spectrum SPF 15 with intellishield

Jafra

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

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avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-118	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
LAURETH-7 (UNII: Z95S6G8201)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
GLYCERIN (UNII: PDC6A3C0OX)		
PHENO XYETHANOL (UNII: HIE492ZZ3T)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)		
MUNG BEAN (UNII: 1LIB31N73G)		
EDETATE TRISO DIUM (UNII: 420 IP9 21MB)		
PANTHENOL (UNII: WV9CM0O67Z)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)		
PEG-4 LAURATE (UNII: AYF4VM3N1Z)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		
CHONDRUS CRISPUS (UNII: OQS23HUA1X)		
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:68828-118-02	1 in 1 BOX	10/26/2012	
l	1 NDC:68828-118-01	75 mL in 1 PACKAGE; 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	10/26/2012	

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-118)	

Revised: 5/2019 Jafra Cosmetics International Inc