

OIL CONTROL TESTERS SPF 15- octinoxate, octisalate, octocrylene lotion
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.

Tester Oil controlling makeup SPF 15

Sunscreen Active ingredient (SPF 15): Octinoxate/Ethylhexyl Methoxycinnamate, Octisalate/Ethylhexyl Salicylate, Oxybenzone/Benzophenone-3

This information is not included

Keep out of reach of children

Discontinue use if signs of irritation occur

Caution: For external use only. Avoid contact with eyes.

This information is not included.

Other ingredients: Water/Aqua, Butylene Glycol, Isopropyl Palmitate, Isopropyl Isostearate, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Glyceryl Stearate, Di-PPG-3 Myristyl Ether Adipate, Silica, Stearic Acid, Zinc Oxide/CI 77497, Polysorbate 20, Lecithin, Polysilicone-11, Laureth-12, Cyclopentasiloxane, Acrylates/Dimethicone Copolymer, DMDM Hydantoin, Trihydroxystearin, Magnesium Aluminum Stearate, Xanthan Gum, Panthenol, Ipomoea Digitata (Fingerleaf Morning Glory) Extract, Withania Somnifera (winter Cherry) Extract, Vigna Radiata (Mung Bean) Extract, Tocopheryl Acetate, Hamamelis Virginia (Witch Hazel) Extract, Symphytum Officinale Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativas (Cucumber) Fruit Extract, Aloe Barbadensis Leaf Extract, Althaea Officinalis Root Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Fragrance/Parfum, Trisodium EDTA, PEG-4 Laurate, Iodopropynyl Butylcarbamate [May contain: Iron Oxides/CI 77491/CI 77492/CI 77499, Titanium Dioxide/CI 77891] [Fragrance/Parfum contains: Limonene, Linalool, Butylphenyl Methylpropional (Lillial), Citronellol]

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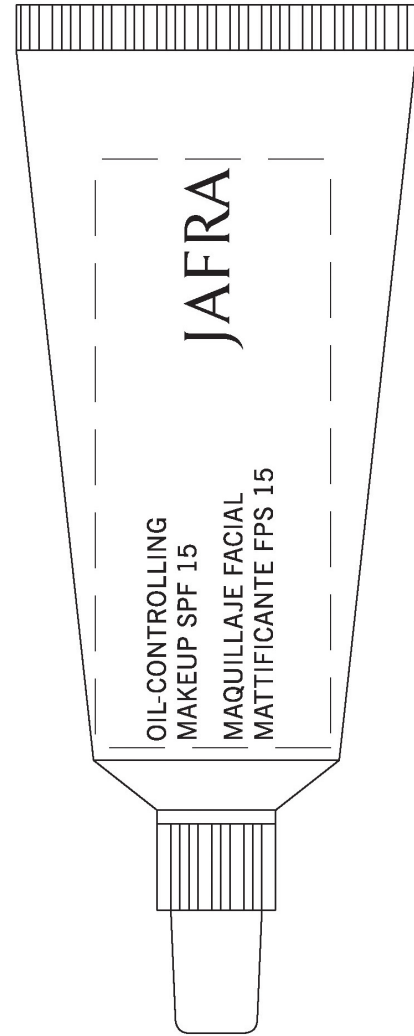
Tester Oil-controlling makeup Makeup SPF 15/ Moisturizing Makeup SPF 15

Muestrario de Maquillaje Facial Matificante *FPS 15 / Maquillage Facial Humectante *FPS 15

Contains: 10 testers at .27 Fl Oz each

Contenido: 10 pzas de 8 ml c/u / 80 ml

80 ml 2.7 Fl Oz (US)



OIL CONTROL TESTERS SPF 15

octinoxate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.8 g in 80 mL
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	2.4 g in 80 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	1.6 g in 80 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
LAURETH-12 (UNII: OAH19558U1)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PANTHENOL (UNII: WV9CM0O67Z)	
WITHANIA SOMNIFERA FLOWER (UNII: 2HZ95R7082)	
MUNG BEAN (UNII: 1LIB31N73G)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
COMFREY LEAF (UNII: DG4F8T839X)	
MATRICARIA RECUTITA LEAF (UNII: 6I9LN466F0)	
CUCUMBER (UNII: YY7C30VXJT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
TEA TREE OIL (UNII: VIF565UC2G)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-105-01	10 in 1 BOX	06/05/2012	
1		8 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 not final	part352	06/05/2012	

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(68828-105)

Revised: 6/2019

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