OIL-FREE FACIAL SUNSCREEN SPECTRUM SPF 50 JAFRA- avobenzone, homosalate, 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.

Sun Oil-Free Facial Sunscreen Broad Spectrum SPF 50

Active Ingredients	**Purpose**
Avobenzone 3.0%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen

- 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

Warning

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Risne 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 the risk, regularly use sunscreen with a Broad Sectrum SPF 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

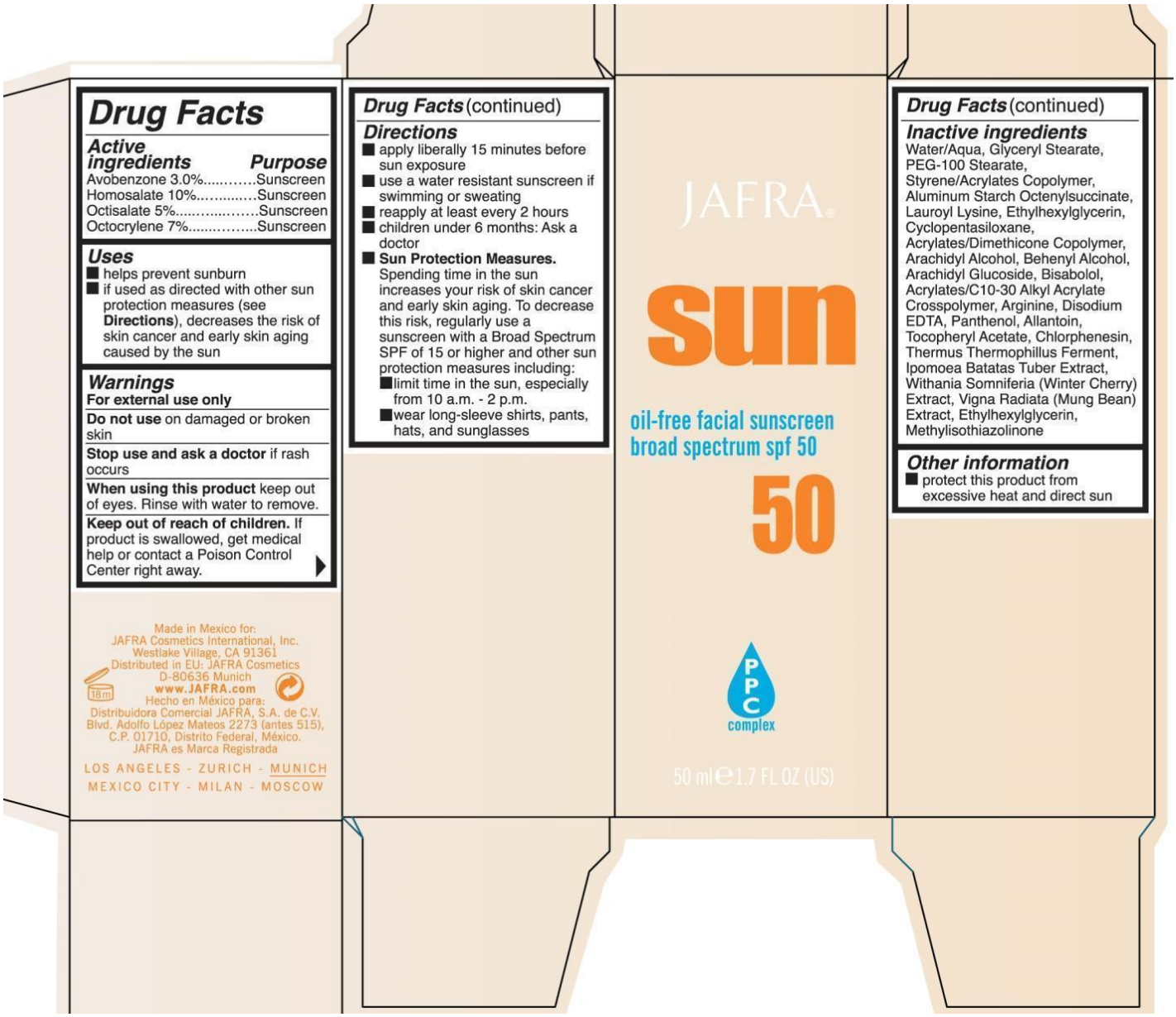
Inactive ingredients

Water/Aqua, Glyceryl Stearate, PEG- 100 Stearate, Styrene/Acrylates Copolymer, Aluminum Starch Octenylsuccinate, Lauroyl Lysine, Ehtylhexylglycerin, Cyclopentasiloxane, Acylates/Dimethicone Copolymer, Arachidyl Alcohol, Behenyl Alcohol, Arachidyl Glucoside, Bisabolol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arginine, Disodium EDTA, Panthenol, Allantoin, Tocopheryl Acetate, Chlorphenesin, Thermus Thermophillus Ferment, Ipomoea Batatas Tuber Extract, Withania Somniferia (Winter Cherry) Extract, Vigna Radiata (Mug Bean)
Extract, Ethylhexylglycerin, Methylisothiazolinone

JAFRA

SUN

Oil-Free Facial Sunscreen Broad Spectrum SPF 50



OIL-FREE FACIAL SUNSCREEN SPECTRUM SPF 50 JAFRA

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68828-215
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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
LAUROYL LYSINE (UNII: 113171Q70B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
LEVOMENOL (UNII: 24WE03BX2T)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ARGININE (UNII: 94ZLA3W45F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
SWEET POTATO (UNII: M9WGG9Z9GK)	
MUNG BEAN (UNII: 1LIB31N73G)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68828-215-02	1 in 1 CARTON	02/13/2015	
1	NDC:68828-215-01	50 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	02/13/2015	

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(68828-215)

Revised: 5/2019

JAFRA COSMETICS INTERNATIONAL