# ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 COCOA- homosalate, octis alate, zinc oxide 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.

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#### Always Foundation Makeup Broad Spectrum SPF 15 Cocoa

Homosalate 4.25% Purpose Sunscreen

Octisalate 4.75% Purpose Sunscreen

Zinc Oxide 7.0% Purpose 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.

#### For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

**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 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

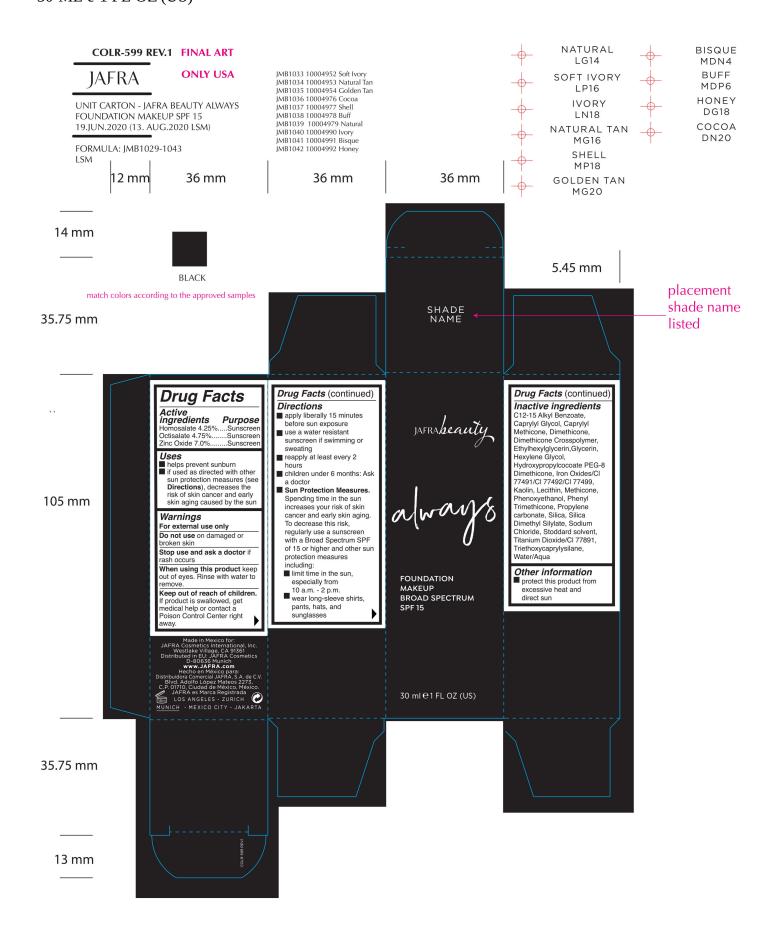
C12-15 Alkyl Benzoate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethicone Crosspolymer, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcocoate PEG-8 Dimethicone, Iron Oxides/CI 77491/CI 77492/CI 77499, Kaolin, Lecithin, Methicone, Phenoxyethanol, Phenyl Trimethicone, Propylene carbonate, Silica, Silica Dimethyl Silylate, Sodium Chloride, Stoddard solvent, Titanium Dioxide/CI 77891, Triethoxycaprylysilane, Water/Aqua

Protect this product from excessive heat and direct sun.

JAFRA beauty

Always

Foundation Makeup



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homosalate, octisalate, zinc oxide cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68828-431

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.25 g in 100 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	4.75 g in 100 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WHITE SPIRIT TYPE 1 (UNII: 37LNJ1I16R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
KAOLIN (UNII: 24H4NWX5CO)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
PROPYLENE CARBONATE (UNII: 8 D0 8 K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

	Packaging					
ı	# Iter	n Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ı	1 NDC:68	828-431-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	08/20/2020			

# Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment					
Name	Address	ID/FEI	Business Operations		
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture (68828-431)		

Revised: 8/2020 JAFRA COSMETICS INTERNATIONAL