

FRE BROAD SPECTRUM- avobenzone, homosalate, octisalate, octocrylene cream
Emilia Personal Care 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.

FRE Protect Me Facial SPF30

Active ingredients

Avobenzon 3.0%

Homosalate, 8.0%

Octisalate, 4.0%

Octocrylene, 2.0%

Purpose

Sunscreen

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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.

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 **-Stop use and ask a doctor** if rash occurs -

Keep out of reach of children. If

swallowed, get medical help or contact a Poison Control Center right away.

Directions -apply liberally 15 minutes before sun exposure -reapply at least every 2 hours. -use water resistant sunscreen if swimming or sweating. -children under 6 months of age: 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 10 a.m. - 2 p.m. -wear long-sleeved shirts, pants, hats and sunglasses

Inactive ingredients water, glycerin, styrene/acrylates copolymer, glyceryl

stearate, PEG-100 stearate, cetearyl alcohol, cetearyl glucoside, caprylyl methicone, dimethicone, trisiloxanane,

argania spinosa kernel oil, ascorbyl glucoside,

phenoxyethanol, ethylhexylglycerin, potassium cetyl

phosphate, hydrogenated palm glyceride, diethylhexyl

2,6-naphthalate, behenyl alcohol, argania spinosa leaf extract, maltodextrin, panthenol (pro-vitamin B5), butylene glycol, pentylene glycol, hydroxyphenol propamidobenzoic acid, polymethyl methacrylate, fragrance, disodium EDTA, xanthan gum, tocopheryl acetate (vitamin E), bisabolol, camosine, BHT, retinyl palmitate (vitamin A), chamomilla recutita (matricaria) flower extract, melissa officinalis leaf extract, aspalathus linearis (rooibos) leaf extract, tilia vulgaris (linden blossom) flower extract

[illegible]



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42421-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.8 g in 60 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.8 g in 60 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.4 g in 60 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.2 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
STYRENE (UNII: 44LJ2U959V)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ARGAN OIL (UNII: 4V59G5UW9X)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PANTHENOL (UNII: WV9CM0O67Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CHAMOMILE (UNII: FGL3685T2X)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
TILIA X EUROPAEA FLOWER (UNII: NHV2K1OUDH)	
CARNOSINE (UNII: 8HO6PVN24W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42421-600-60	60 mL in 1 TUBE; Type 0: Not a Combination Product	06/28/2016	
2	NDC:42421-600-20	20 mL in 1 TUBE; Type 0: Not a Combination Product	08/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/28/2016	

Labeler - Emilia Personal Care Inc (965445112)