

FRE PROTECT BODY BROAD SPECTRUM SPF30- avobenzone, homosalate, octisalate, octocrylene cream

Emilia Cosmetics Ltd

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 Body Broad Spectrum SPF30

Drug Facts

Active Ingredients

Avobenzone, 3%

Homosalate, 10%

Octisalate, 5%

Octocrylene, 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases 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 Centre 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 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.

Other Information

- protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

water, propanediol, coco-caprylate, diethylhexyl 2,6-naphthalate C12-15 alkyl benzoate, oryza sativa (rice) starch, phenoxyethanol, ethylhexylglycerin, tricontanyl PVP, glycerin, argania spinosa leaf extract, aloe barbadensis leaf juice, polyglyceryl-10 pentastearate, behenyl alcohol, sodium stearyl lactylate, potassium cetyl phosphate, fragrance, xanthan gum, acrylate/C10-30 alkyl acrylate crosspolymer, allantoin, tocopheryl acetate (vitamin E), argania spinosa kernel oil, sodium phytate, butylene glycol, pentylene glycol, hydroxyphenyl propamidobenzoic acid, panthenol (pro-vitamin B5), sodium hydroxide, argania spinosa sprout cell extract, isomalt, lecithin, sodium benzoate.

Package Labeling:

<p>696303118124</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th style="text-align: left;">Active Ingredients</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone, 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate, 10%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate, 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene, 10%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses - helps prevent sunburn - if used as directed with other sun protection measures (see Directions), decreases risk of skin cancer and early skin aging caused by the sun.</p> <p>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 Centre right away.</p> <p>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 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.</p>	Active Ingredients	Purpose	Avobenzone, 3%	Sunscreen	Homosalate, 10%	Sunscreen	Octisalate, 5%	Sunscreen	Octocrylene, 10%	Sunscreen	<p>Distributed by: Fré Skincare, 1121 Industrial Pkwy, Brick NJ 08724 Phone: +1 201-585-8730 freskincare.com, Made in Israel</p>	 
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<p>PROTECT BODY</p> <p>Defense Moisturizing Lotion</p> <p>Formulated for skin that sweats</p> <p>With Argania Active Complex</p> <p>Broad Spectrum SPF30</p> <p>5.07 fl. Oz (150mL)</p>													
<p>FRE PROTECT BODY BROAD SPECTRUM SPF30</p> <p>avobenzone, homosalate, octisalate, octocrylene cream</p>													

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43219-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPANEDIOL (UNII: 5965N8W85T)	
CO CO-CAPRYLATE (UNII: 4828G836N6)	
STARCH, RICE (UNII: 4DGK8B7BS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)	
DOCOSANOL (UNII: 9G1OE216XY)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ARGAN OIL (UNII: 4V59G5UW9X)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
PANTHENOL (UNII: WV9CM0O67Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ISOMALT (UNII: S870P55O2W)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43219-052-05	150 mL in 1 TUBE; Type 0: Not a Combination Product	05/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/15/2019	

Labeler - Emilia Cosmetics Ltd (600076624)

Establishment

Name	Address	ID/FEI	Business Operations
Emilia Cosmetics Ltd		600076624	manufacture(43219-052) , label(43219-052)

Revised: 5/2020

Emilia Cosmetics Ltd