

**MILANI SPF BFF 30 PRIMER- avobenzone, octinoxate, octocrylene, oxybenzone cream**  
**New Milani Group, LLC**

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**Milani SPF BFF 30 Primer**

***Drug Facts***

***Active ingredients***

Avobenzone 3%, Octinoxate 7.3% Octocrylene 3% Oxybenzone 2%

***Purpose***

Sunscreen

***Uses***

- helps prevent sunburn
- if used as directed with other sun protection measures (see ), decreases the risk of skin cancer and early skin aging caused by the sun

***Directions***

***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 generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

- children under 6 months of age: Ask a doctor.
- 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: **Sun Protection Measures.**
- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, and sunglasses

**Other information**

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

**Inactive ingredients:**

Water, Glycerin, Isohexadecane, Sodium Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, PEG-8, Polysorbate 80, Xanthan Gum, Tocopherol, Glycine Soja (Soybean) Oil, Retinyl Palmitate, Ethylhexylglycerin, Citric Acid, Disodium EDTA, Phenoxyethanol, Yellow 5, Red 40.

**Questions or comments?**

Call 866-789-8002 Monday - Friday (7 a.m. to 3:30 p.m. PST)

**Package Labeling:**

**SPF BFF**  
**SPF 30 PRIMER**  
 BROAD SPECTRUM SUNSCREEN +  
 UVA/UVB PROTECTION

LIGHTWEIGHT  
 LOTION TEXTURE

NATURAL FINISH

ENHANCED WITH  
 VITAMIN E AND  
 GLYCERIN

SMOOTHES SKIN • ALL SKINTONES  
 • EXTENDS MAKEUP WEAR

**MILANI**

**Drug Facts**  
**Purpose**  
 Avobenzone 3%.....Sunscreen  
 Octinoxate 7.3%.....Sunscreen  
 Octocrylene 3%.....Sunscreen  
 Oxybenzone 2%.....Sunscreen

7 17489 45701 9  
 MADE IN US WITH NON-US COMPONENTS  
 Peel for drug facts

**Drug Facts**  
 (continued)  
**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 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 generously and evenly 15 minutes

**Drug Facts**  
 (continued)  
**Drug Facts**  
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 before sun exposure  
 • reapply at least every 2 hours  
 • use a water-resistant sunscreen if swimming or sweating  
 • children under 6 months of age: Ask a doctor.  
 • **Sun Protection Measures.** spending time in 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, and sun glasses

**Drug Facts**  
 (continued)  
**Other information**  
 • Protect the product in this container from excessive heat and direct sun

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 Monday – Friday  
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DIST. BY MILANI,  
 LOS ANGELES, CA 90058

Lift

Non Printing Area

MILANI

SPF BFF

**SPF 30 PRIMER**

BROAD SPECTRUM  
SUNSCREEN +  
UVA/UVB PROTECTION

**BASE FPS 30**

ÉCRAN SOLAIRE À  
LARGE SPECTRE +  
PROTECTION UVA/UVB

1.0 U.S. FL. OZ. / 30 mL

Non Printing Area

**MILANI SPF BFF 30 PRIMER**

avobenzone, octinoxate, octocrylene, oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71435-0001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	73 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>SODIUM ACRYLATE</b> (UNII: 7C98FKB43H)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE</b> (UNII: 2T9Q6EKI0G)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71435-0001-0	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M020	01/01/2020	

**Labeler** - New Milani Group, LLC (120923342)