

**MALIN AND GOETZ SPF 30 FACE MOISTURIZER- avobenzone, homosalate, octinoxate, octisalate, and oxybenzone cream**

**Malin + Goetz**

*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.*

-----

**Malin and Goetz  
SPF 30 Face Moisturizer**

Drug Facts

<b>Active Ingredient</b>	<b>Purpose</b>
avobenzone 3%	sunscreen
homosalate 10%	sunscreen
octinoxate 7.5%	sunscreen
octisalate 5%	sunscreen
oxybenzone 5%	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

**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 or irritation develops and lasts

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 to clean face
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- 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
- Children under 6 months of age: Ask a doctor. Smooth onto face and neck until thoroughly absorbed

**Inactive Ingredients**

Water (aqua), c12-15 alkyl ethylhexanoate, dimethicone, glycerin, vp/eicosene copolymer, phenoxyethanol, peg-20 methyl glucose sesquistearate, methyl glucose sesquistearate, cetyl alcohol,

potassium cetyl phosphate, acrylates/c10-30 alkyl acrylate cross- polymer, peg-40 stearate, chlorphenesin, polysorbate 80, cholesterol, ethylhexylglycerin, sodium benzoate, sodium hydroxide, disodium edta, methylisothiazolinone, panthenol, tetrahexyldecyl ascorbate, aloe barbadensis leaf juice powder, allantoin, tocopherol, camellia oleifera leaf extract, epilobium angustifolium flower/leaf/stem extract

### **Other information**

- protect this product from excessive heat and direct sun

### **Questions or comments?**

Visit [www.malinandgoetz.com](http://www.malinandgoetz.com) or call +1-212-244-7771, M-F, 9am-6pm EST

DISTRIBUTED BY:  
MALIN+GOETZ INC.,  
210 WEST 29TH ST.,  
NEW YORK, NEW YORK 10001

### **PRINCIPAL DISPLAY PANEL - 48 mL Tube Carton**

(MALIN+GOETZ)  
spf 30 face moisturizer.

BROAD SPECTRUM SPF 30. ALL SKIN TYPES.  
APOTHECARY AND LAB—FM-118-48.

BROAD SPECTRUM SPF 30 HELPS PROTECT AGAINST SUN DAMAGE WHILE GREEN TEA ANTIOXIDANTS PROVIDE PROTECTION AGAINST ENVIRONMENTAL TOXINS AND FREE RADICALS. GENTLY MOISTURIZES AND BALANCES ALL SKIN TYPES. NATURAL FRAGRANCE AND COLOR. DIRECTIONS: APPLY GENEROUSLY AND EVENLY TO CLEAN FACE 15 MINUTES BEFORE SUN EXPOSURE. USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING. REAPPLY AT LEAST EVERY 2 HOURS. CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR. SMOOTH ONTO FACE AND NECK UNTIL THOROUGHLY ABSORBED. 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 OR IRRITATION DEVELOPS AND LASTS. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY. FORMULATED AND DISTRIBUTED BY: MALIN+GOETZ INC., 210 WEST 29TH ST., NEW YORK, NEW YORK 10001, TEL +1 212 244 7771. WWW.MALINANDGOETZ.COM. MALIN+GOETZ DOES NOT TEST ON ANIMALS. MADE IN USA.

1.7fl.oz.e48ml

# (MALIN+GOETZ) spf 30 face moisturizer.

**BROAD SPECTRUM SPF 30, ALL SKIN TYPES.  
APOTHECARY AND LAB—FM-118-48.**

**BROAD SPECTRUM SPF 30 HELPS PROTECT AGAINST SUN DAMAGE WHILE GREEN TEA ANTI-OXIDANTS PROVIDE PROTECTION AGAINST ENVIRONMENTAL TOXINS AND FREE RADICALS. GENTLY MOISTURIZES AND BALANCES ALL SKIN TYPES. NATURAL FRAGRANCE AND COLOR. DIRECTIONS: APPLY GENEROUSLY AND EVENLY TO CLEAN FACE 15 MINUTES BEFORE SUN EXPOSURE. USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING. REAPPLY AT LEAST EVERY 2 HOURS. CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR. SMOOTH ONTO FACE AND NECK UNTIL THOROUGHLY ABSORBED. 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 OR IRRITATION DEVELOPS AND LASTS. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY. FORMULATED AND DISTRIBUTED BY: MALIN+GOETZ INC., 210 WEST 29TH ST., NEW YORK, NEW YORK 10001, TEL +1 212 244 7771. WWW.MALINANDGOETZ.COM. MALIN+GOETZ DOES NOT TEST ON ANIMALS. MADE IN USA.**

**1.7fl.oz. e 48ml**

## Drug Facts

Active Ingredient	Purpose
avobenzone 3%	.....sunscreen
homosalate 10%	.....sunscreen
octinoxate 7.5%	.....sunscreen
octisalate 5%	.....sunscreen
oxybenzone 5%	.....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

### 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 or irritation develops and lasts

**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 to clean face
- Use a water resistant sunscreen if swimming or sweating ■ Reapply at least every 2 hours
- **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
  - Children under 6 months of age: Ask a doctor. Smooth onto face and neck until thoroughly absorbed

## Drug Facts (continued)

### Inactive Ingredients

Water (aqua), c12-15 alkyl ethylhexanoate, dimethicone, glycerin, vp/eicosene copolymer, phenoxyethanol, peg-20 methyl glucose sesquistearate, methyl glucose sesquistearate, cetyl alcohol, potassium cetyl phosphate, acrylates/c10-30 alkyl acrylate cross-polymer, peg-40 stearate, chlorphenesin, polysorbate 80, cholesterol, ethylhexylglycerin, sodium benzoate, sodium hydroxide, disodium edta, methylisothiazolinone, panthenol, tetrahexyldecyl ascorbate, aloe barbadensis leaf juice powder, allantoin, tocopherol, camellia oleifera leaf extract, epilobium angustifolium flower/leaf/stem extract

### Other information

- protect this product from excessive heat and direct sun

(MALIN+GOETZ)®



## MALIN AND GOETZ SPF 30 FACE MOISTURIZER

avobenzone, homosalate, octinoxate, octisalate, and oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53634-254
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>avobenzone</b> (UNII: G63QQF2NOX) (avobenzone - UNII:G63QQF2NOX)	avobenzone	30 mg in 1 mL
<b>homosalate</b> (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	100 mg in 1 mL
<b>octinoxate</b> (UNII: 4Y5P7MUD51) (octinoxate - UNII:4Y5P7MUD51)	octinoxate	75 mg in 1 mL
<b>octisalate</b> (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	50 mg in 1 mL
<b>oxybenzone</b> (UNII: 95OOS7VE0Y) (oxybenzone - UNII:95OOS7VE0Y)	oxybenzone	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>c12-15 alkyl ethylhexanoate</b> (UNII: GQJ580CH83)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>peg-20 methyl glucose sesquistearate</b> (UNII: 0345752X7U)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>peg-40 stearate</b> (UNII: ECU18C66Q7)	
<b>chlorphenesin</b> (UNII: I670DAL4SZ)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>methylisothiazolinone</b> (UNII: 229D0E1QFA)	
<b>panthenol</b> (UNII: WV9CM0O67Z)	
<b>tetrahexyldecyl ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>aloe vera leaf</b> (UNII: ZY81Z83H0X)	
<b>allantoin</b> (UNII: 344S277G0Z)	
<b>tocopherol</b> (UNII: R0ZB2556P8)	
<b>camellia oleifera leaf</b> (UNII: 5077EL0C60)	
<b>epilobium angustifolium flowering top</b> (UNII: 08H094218D)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-254-50	1 in 1 CARTON		
1		48 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 NOT FINAL	part352	01/01/2014	

**Labeler** - Malin + Goetz (138615930)

**Registrant** - Milbar Laboratories, Inc. (195556790)

**Establishment**

Name	Address	ID/FEI	Business Operations
Milbar Laboratories, Inc.		195556790	MANUFACTURE(53634-254)

Revised: 8/2014

Malin + Goetz