

SPF 30 FACE MOISTURIZER- avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion
Malin and Goetz 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.

SPF 30 Face Moisturizer

Active Ingredient	Purpose
Avobenzone 3%	sunscreen
Homosalate 10%	sunscreen
Octinoxate 7.5%	sunscreen
Octisalate 2.75%	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
- Retains SPF up to 80 minutes of activity in the water

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away

Stop use and ask a doctor if: Rash or irritation develops and lasts.

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.

Directions

- Apply liberally and evenly to dry skin 15 minutes before sun exposure and as often as needed.
- Re-apply at least every 2 hours; after 80 minutes of swimming or perspiring; immediately after towel drying.
- Children under 6 months of age, consult your physician
- **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 from 10am-2pm
 - wear long sleeve shirts, pants, hats and sunglasses

Water(Aqua), Butyloctyl Salicylate, Dimethicone, Corn Start Modified, Hexylene Glycol, VP/Eicosene Copolymer, Glycerin, Cetearyl Alcohol, PEG-12 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Panthenol, Allantoin, Aloe Barbadensis Leaf Juice Powder, Butyrospermum Parkii (shea) Oil, Epilobium Angustifolium Flower/leaf/stem extract, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sorbitan Stearate, Xanthan Gum, Caprylyl Glycol, Ethylhexylglycerin, Calcium Pantothenate, Sodium Hydroxide, Chlorphenesin, Disodium EDTA, Potassium Sorbate, PEG-40 Stearate, Phenoxyethanol

(Malin + Goetz)

SPF 30 Face Moisturizer

Broad Spectrum SPF 30 All skin types

Water Resistant

1.7 fl. oz. 50 ml

(MALIN+GOETZ) spf 30 face moisturizer.

**BROAD SPECTRUM SPF 30. ALL SKIN TYPES.
WATER RESISTANT—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. DIRECTIONS: APPLY GENEROUSLY AND EVENLY TO CLEAN FACE 15 MINUTES BEFORE SUN EXPOSURE. 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. MALIN+GOETZ INC., 330 SEVENTH AVENUE, NEW YORK, NY 10001, TEL +1 212 244 7771, WWW.MALINANDGOETZ.COM. MADE IN USA.

1.7 fl.oz. e 50ml

(MALIN+GOETZ)®



Drug Facts

Active Ingredient	Purpose
avobenzene 3%sunscreen
homosalate 10%sunscreen
octinoxate 7.5%sunscreen
octisalate 2.75%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
- Retains SPF up to 80 minutes of activity in the water

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 liberally and evenly to dry skin 15 minutes before sun exposure and as often as needed.
- Re-apply at least every two hours; after 80 minutes minutes of swimming or perspiring; immediately after towel drying.
- Children under 6 months of age, consult your physician
- **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 10am-2pm
 - wear long-sleeve shirts, pants, hats, and sunglasses.

Drug Facts (continued)

Inactive Ingredients
Water (Aqua), Butyloctyl Salicylate, Dimethicone, Corn Starch Modified, Hexylene Glycol, VP/Eicosene Copolymer, Glycerin, Cetearyl Alcohol, PEG-12 Dimethicone, Tetrahydroxyl Decyl Ascorbate, Tocopheryl Acetate, Panthenol, Allantoin, Aloe Barbadensis Leaf Juice Powder, Butyrospermum Parkii (Shea) Oil, Epilobium Angustifolium Flower/Leaf/Stem Extract, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sorbitan Stearate, Xanthan Gum, Caprylyl Glycol, Ethylhexylglycerin, Calcium Pantothenate, Sodium Hydroxide, Chlorphenesin, Disodium EDTA, Potassium Sorbate, PEG-40 Stearate, Phenoxyethanol

Other information
■ protect this product from excessive heat and direct sun.

Expiration & lot number here

(MALIN+GOETZ)

spf 30 face moisturizer.

BROAD SPECTRUM SPF 30, ALL SKIN TYPES.
WATER-RESISTANT—FM-118-48.

1.7fl.oz. e 50ml



(MALIN+GOETZ)®

BROAD SPECTRUM SPF 30 HELPS PROTECT AGAINST SUN DAMAGE WITH ANTI-OXIDANT VITAMIN E. GENTLY MOISTURIZES AND BALANCES ALL SKIN TYPES. SPF 30 FACE MOISTURIZER HAS A NATURAL FRAGRANCE AND COLOR.

CAUTION: 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 LIBERALLY AND EVENLY TO DRY SKIN, 15 MINUTES BEFORE SUN EXPOSURE AND AS OFTEN AS NEEDED. RE-APPLY AT LEAST EVERY TWO HOURS; AFTER 80 MINUTES OF SWIMMING OR RE-SPIRING; IMMEDIATELY AFTER TOWEL DRYING. CHILDREN UNDER 6 MONTHS OF AGE, CONSULT YOUR PHYSICIAN BEFORE USING THIS PRODUCT. TO DECREASE 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 10AM-2PM; WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUNGLASSES. ACTIVE INGREDIENTS: AVOBENZONE 3% - SUNSCREEN; HOMOSALATE 10% - SUNSCREEN; OCTINOXATE 7.5% - SUNSCREEN; OCTOCRYLENE 2.75% - SUNSCREEN; OXYBENZONE 5% - SUNSCREEN. MALIN+GOETZ INC., 330 SEVENTH AVENUE, NEW YORK, NY 10001, TEL +1 212 244 7771, WWW.MALINANDGOETZ.COM. MADE IN USA.



SPF 30 FACE MOISTURIZER

avobenzene, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53634-255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.75 in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE FEROX LEAF (UNII: 0D145J8EME)	
SHEANUT OIL (UNII: O88E196QRF)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-255-02	1 in 1 CARTON	12/05/2017	
1	NDC:53634-255-01	50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/05/2017	

Labeler - Malin and Goetz Inc (138615930)

Establishment

Name	Address	ID/FEI	Business Operations
Milbar Laboratories, Inc.		195556790	manufacture(53634-255)

Revised: 1/2021

Malin and Goetz Inc