

**MALIN AND GOETZ SPF 15 FACE MOISTURIZER- octinoxate, octisalate, oxybenzone cream
Malin & 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 15 face moisturizer

Active ingredients purpose

Octinoxate 7.5% Sunscreen

Octisalate 5% Sunscreen

Oxybenzone 2% Sunscreen

Uses

For skin highly sensitive for sunburn

helps prevent sunburn

higher SPF gives more sunburn protection

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

Stop use and ask a doctor if skin rash occurs

Warnings

For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing and using a sunscreen

Directions

Apply liberally before sun exposure. Apply and reapply as directed to avoid lowering protection. Reapply at least every 2 hours. Children under 6 months: Ask a doctor

Water (Aqua), Octyl Dodecyl Neopentanoate, Isocetyl stearate, glycerin, cetyl alcohol, glyceryl stearate, PEG-100 Stearate, Persea Gratissima (Avocado) Oil, Phytosterols, Olea Europaea (olive) Fruit oil, Butyrospermum Parkii (Shea butter), Ormenis Multicaulis, Tocopheryl Acetate, Butylene Glycol, Camellia Oleifera Leaf Extract, Magnesium Ascorbyl Phosphate, Cyano-cobalamin, Cholecalciferol, Retinyl Palmitate, C13-C16 Isoparaffin, C12-C14 Isoparaffin, C13-C15 Alkane, Titanium Dioxide, Polysorbate 80, Carbomer, Triethanolamine, phenoxyethanol, Sodium Dehydroacetate.

(MALIN+GOETZ)

spf 15 face moisturizer.

**UVA+UVB BROAD SPECTRUM. ALL SKIN TYPES.
FATTY ACID ABSORPTION TECHNOLOGY—FM-110-04.**

NATURAL VITAMINS E, A, B, C AND D SYNTHESIZE ABSORBENT, RESIDUE-FREE FATTY ACIDS TO GENTLY AND EFFECTIVELY HYDRATE AND BALANCE ALL SKIN TYPES. BROAD SPECTRUM SPF 15 AND ANTIOXIDANTS HELP CREATE A BARRIER AGAINST SUN DAMAGE, ENVIRONMENTAL TOXINS AND FREE RADICALS WITHOUT PORE-CLOGGING OILS AND PARABENS. NOURISHING SHEA BUTTER AND SOOTHING CHAMOMILE HELP RETAIN MOISTURE AND REDUCE IRRITATION. NATURAL FRAGRANCE AND COLOR. DIRECTIONS: AFTER CLEANSING, APPLY A SMALL AMOUNT OF CONCENTRATED MOISTURIZER ONTO FACE. AVOID EYES, OILY AREAS AND OVER-MOISTURIZING. INCREASE APPLICATION FOR DRYER AREAS. CAUTION: FOR EXTERNAL, ADULT USE ONLY. IF IRRITATION OCCURS, DISCONTINUE USE. AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES WITH WATER. ACTIVE INGREDIENTS: OCTINOXATE 7.5%, OCTISALATE 5.0%, OXYBENZONE 2.0%. OTHER INGREDIENTS: PURIFIED WATER (AQUA PURIFICATA), OCTYL DODECYL NEOPENTANOATE, ISOCETYL STEARATE, GLYCERIN, CETYL ALCOHOL, GLYCERYL STEARATE, PEG-100 STEARATE, PERSEA GRATISSIMA (AVOCADO) OIL, PHYTOSTEROLS, OLEA EUROPAEA (OLIVE) FRUIT OIL, BUTYROSPERMUM PARKII (SHEA BUTTER), ORMENIS MULTICAULIS OIL, TOCOPHERYL ACETATE (VITAMIN E), BUTYLENE GLYCOL, CAMELLIA OLEIFERA LEAF EXTRACT, MAGNESIUM ASCORBYL PHOSPHATE (STABLE VITAMIN C), CYANOCOBALAMIN, CHOLECALCIFEROL, RETINYL PALMITATE (VITAMIN A), C13-C16 ISOPARAFFIN, C12-C14 ISOPARAFFIN, C13-C15 ALKANE, TITANIUM DIOXIDE, POLYSORBATE 80, CARBOMER, TRIETHANOLAMINE, PHENOXYETHANOL, SODIUM DEHYDROACETATE. FORMULATED AND DISTRIBUTED BY: MALIN+GOETZ INC., 210 WEST 29TH STREET, NEW YORK, NY 10001, TEL +1 212 244 7771, WWW.MALINANDGOETZ.COM. EU: PROFUMIMPORT SRL, VIA BRERA 6, 20121, MILAN, ITALY. MALIN+GOETZ DOES NOT TEST ON ANIMALS. MADE IN USA.

4fl.oz.e118ml.

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Oxybenzone 2%.....	Sunscreen

Uses ■ for skin highly sensitive to sunburn ■ helps prevent sunburn ■ higher SPF gives more sunburn protection

Warnings

For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if skin rash occurs.

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

Directions

■ apply liberally before sun exposure ■ apply and reapply as directed to avoid lowering protection ■ reapply at least every 2 hours ■ children under 6 months: ask a doctor

Other Ingredients

Water (Aqua), Octyl Dodecyl Neopentanoate, Isocetyl Stearate, Glycerin, Cetyl Alcohol, Glyceryl Stearate, Peg-100 Stearate, Persea Gratissima (Avocado) Oil, Phytosterols, Olea Europaea (Olive) Fruit Oil, Butyrospermum Parkii (Shea Butter), Ormenis Multicaulis Oil, Tocopheryl Acetate, Butylene Glycol, Camellia Oleifera Leaf Extract, Magnesium Ascorbyl Phosphate, Cyano- cobalamin, Cholecalciferol, Retinyl Palmitate, C13-C16 Isoparaffin, C12-C14 Isoparaffin, C13-C15 Alkane, Titanium Dioxide, Polysorbate 80, Carbomer, Triethanolamine, Phenoxyethanol, Sodium Dehydroacetate.



(MALIN+GOETZ)®

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spf 15 face moisturizer.

UVA +UVB Broad Spectrum. All skin types. Fatty Acid Absorption technology-FM-110-04

4 fl. oz. e 118ml.

MALIN AND GOETZ SPF 15 FACE MOISTURIZER

octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53634-152
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SHEA BUTTER (UNII: K49155WL9Y)	
CLADANTHUS MIXTUS FLOWER VOLATILE OIL (UNII: RAY2FRM711)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOMER 934 (UNII: Z135WT9208)	
trolamine (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-152-01	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/02/2012	

Labeler - Malin & Goetz Inc (138615930)

Registrant - Malin & Goetz Inc (138615930)

Establishment

Name	Address	ID/FEI	Business Operations
D'ARCY ACQUISITION, LLC		101381952	manufacture(53634-152)

