

TIMELESS ILLUMINATING MAKEUP SPF 30 SESAME MERLE NORMAN- octinoxate, oxybenzone cream

Merle Norman Cosmetics, 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.

Timeless Illuminating Makeup Broad Spectrum SPF 30

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Oxybenzone 2.0%	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

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 occurs

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

- For sunscreen use:
 - apply liberally and evenly 15 minutes before sun exposure
 - 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, regular 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 10a.m. - 2p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Water/Aqua/Eau, Cyclopentasiloxane, Titanium Dioxide (CI 77891). Caprylic/Capric Triglyceride, Phenyl Trimethicone, Methyl Trimethicone, Aluminum Oxide, Lauryl PEG-10 Tris(trimethylsiloxy)silyethyl Dimethicone, Trimethylsiloxy silicate, Dimethicone, Butylene Glycol, Glycerin, Gold, Palmitoyl Hexapeptide-14, Peat Extract, Diglycosyl Gallic Acid, Hydroxyethylcellulose, Saccharomyces/Xylinum/Black Tea Ferment, HDI/Trimethylol Hexyllactone Crosspolymer, Polymethylsiloxane, Triethoxycaprylylsilane, Bis-Stearyl Dimethicone, PEG-9 Polydimethylsiloxyethyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dextrin Palmitate,

Caprylyl Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Polyglyceryl-3Beeswax, Silica, Mica (CI 77019), Ethoxydiglycol, Magnesium Sulfate, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Phenoxyethanol, Tetrasodium EDTA, Potassium Sorbate, Talc, **May Contain**

Barium Sulfate (CI 77120), Bismuth Oxochloride (CI 77163), Iron Oxides (CI 77489, CI 77491, CI 77492, CI 77499), Ultramarines (CI 77007)

Timeless Illuminating Makeup

Broad Spectrum SPF 30

Merle Norman

30 mL e 1 FL. OZ.

ALAEASTER BEIGE



MERLE NORMAN
WWW.MERLENORMAN.COM

Drug Facts (continued)

Directions

- For sunscreen use:
- apply liberally and evenly 15 minutes before sun exposure
- 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 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
- children under 6 months: Ask a doctor

Mode d'emploi

- Pour vous protéger de soleil:
- appliquez généreusement et uniformément 15 minutes avant de vous mettre au soleil
- utilisez un écran solaire résistant à l'eau si vous nagez ou transpirez
- réappliquez au moins toutes les 2 heures

- **Mesures de protection contre le soleil.** L'exposition au soleil accroît le risque de cancer et de vieillissement prématuré de la peau. Pour amoindrir ce risque, utilisez régulièrement un écran solaire à ample protection FPS 15 ou plus et observez d'autres mesures de protection contre le soleil telles que:

- limiter le temps d'exposition au soleil, surtout entre 10 heures et 14 heures
- porter des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil
- pour les enfants de moins de 6 mois: Consulter un médecin

Inactive (non-medicinal) ingredients:

Water/Aqua/Eau, Cyclopentasiloxane, Titanium Dioxide (CI 77891), Caprylic/Capric Triglyceride, Phenyl Trimethicone, Methyl Trimethicone, Aluminum Oxide, Lauryl PEG-10 Tris(trimethylsiloxy)silyl Methyl Dimethicone, Trimethylsiloxy silicate, Dimethicone, Butylene Glycol, Glycerin, Gold, Palmitoyl Hexapeptide-14, Peat Extract, Diglycosyl Gallic Acid, Hydroxyethylcellulose, Saccharomyces/Xylinum/Black Tea Ferment, HDI/Trimethylol Hexyllactone Crosspolymer, Polymethylsiloxoxane, Triethoxycaprylsilane, Bis-Stearyl Dimethicone, PEG-9 Polydimethylsiloxyethyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dextrin Palmitate, Caprylyl Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Polyglyceryl-3 Beeswax, Silica, Mica (CI 77019), Ethoxydiglycol, Magnesium Sulfate, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Phenoxethanol, Tetrasodium EDTA, Potassium Sorbate, Talc, **May Contain/Peut Contenir (+/-),** Barium Sulfate (CI 77120), Bismuth Oxychloride (CI 77163), Iron Oxides (CI 77489, CI 77491, CI 77492, CI 77499), Ultramarines (CI 77007).

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

1-800-421-2060 9:00 a.m.-5:00 p.m. PST

Dermatologist tested. Fragrance-free. Oil-free. Testé par un dermatologue. Sans parfum. Sans huile.



**TIMELESS
ILLUMINATING
MAKEUP
BROAD SPECTRUM
SPF 30**

**MAQUILLAGE INTEMPOREL
ET LUMINEUX
LARGE SPECTRE FPS 30**

MERLE NORMAN
ESTABLISHED IN LOS ANGELES
SINCE 1931

**30 mL e
1 FL.OZ.**

EMULSION/EMULSION
DI 1985
FPO

Drug Facts

Active (medicinal) ingredients (w/w)	Purpose
Octinoxate 7.5%	Sunscreen
Oxybenzone 2.0%	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

Utilisations

- aide à prévenir les coups de soleil
- amoindrit le risque de cancer et de vieillissement prématuré de la peau causés par le soleil lorsque utilisé comme indiqué en conjonction avec d'autres mesures de protection solaire (voir **Mode d'emploi**).

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.

Avertissements

À usage externe seulement

Ne pas utiliser sur une peau abîmée ou des plaies ouvertes

Faites attention à vos yeux lorsque vous utilisez ce produit. Nettoyez avec de l'eau.

En cas de rougeurs cessez l'utilisation et consultez un médecin

Ne pas laisser à la portée des enfants.

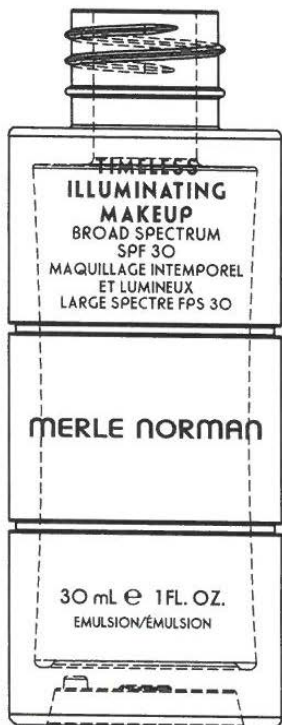
Si vous avalez ce produit, consultez un médecin ou contactez immédiatement un centre antipoison.



MANUFACTURED BY:
MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN USA
IMPORTED BY:
MERLE NORMAN COSMETICS
TORONTO, ONTARIO M1X 1E7

PRINTED IN U.S.A.

017-97-40
R-O



Dermatologist tested.
Testé par un dermatologue.

Directions: Apply liberally and evenly 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Mode d'emploi: Appliquez généreusement et uniformément 15 minutes avant de vous mettre au soleil. Utilisez un écran solaire résistant à l'eau si vous nagez ou transpirez. Réappliquez au moins toutes les 2 heures.

**TIMELESS
ILLUMINATING
MAKEUP
BROAD SPECTRUM
SPF 30
MAQUILLAGE INTEMPOREL
ET LUMINEUX
LARGE SPECTRE FPS 30**

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.

Avertissements: Pour usage externe uniquement. Ne pas utiliser sur une peau abîmée ou des plaies ouvertes. Faites attention à vos yeux lorsque vous utilisez ce produit. Nettoyez avec de l'eau. En cas de rougeurs cessez l'utilisation et consultez un médecin. **No pas laisser à la portée des enfants.** Si vous avalez ce

MERLE NORMAN

produit, consultez un médecin ou contactez immédiatement un centre antipoisson.

Active (Medicinal) Ingredients (W/W): Octinoxate 7.5%, Oxybenzone 2.0%.

MANUFACTURED BY: MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN USA
IMPORTED BY: MERLE NORMAN COSMETICS
TORONTO, ONTARIO M1X 1E7

30 mL e 1FL. OZ.
EMULSION/EMULSION

TIMELESS ILLUMINATING MAKEUP SPF 30 SESAME MERLE NORMAN

octinoxate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-174
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
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GOLD (UNII: 79Y1949PYO)	

HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MICA (UNII: V8A1AW0880)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE SODIUM (UNII: MP1J8420LU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
TALC (UNII: 7SEV7J4R1U)
BARIUM SULFATE (UNII: 25BB7EKE2E)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
FERROUS OXIDE (UNII: G7036X8B5H)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
ULTRAMARINE BLUE (UNII: I39WR998B1)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-174-02	1 in 1 CARTON	01/24/2017	
1	NDC:57627-174-01	30 mL in 1 BOTTLE; 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	01/24/2017	

Labeler - Merle Norman Cosmetics, Inc (008479388)

Registrant - Merle Norman Cosmetics, Inc (008479388)

Establishment			
Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics, Inc		008479388	manufacture(57627-174)

