

**TIMELESS ILLUMINATING MAKEUP SPF 30 PURE BEIGE 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.*

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**Timeless Illuminating Makeup Broad Spectrum SPF 30**

| <b>Active Ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
| 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, Trimethylsiloxyoctyl Dimethicone, Butylene Glycol, Glycerin, Gold, Palmitoyl Hexapeptide-14, Peat Extract, Diglycosyl Gallic Acid, Hydroxyethylcellulose, Saccharomyces/Xylinum/Black Tea Ferment, HDI/Trimethylol Hexyllactone Crosspolymer, Polymethylsiloxane, 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 INTÉMPOREL  
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.**

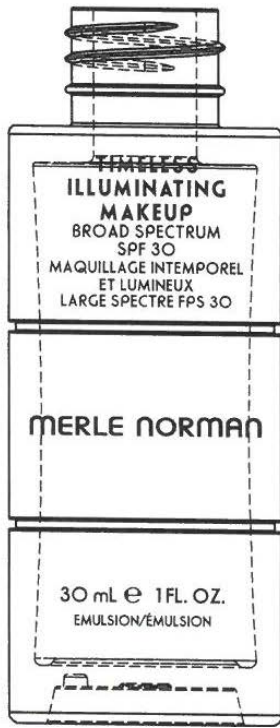
Si vous avalez ce produit, consultez un médecin ou contactez immédiatement un centre antipoison.



**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.

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

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**MERLE NORMAN**

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

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

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30 mL e 1FL. OZ.  
EMULSION/EMULSION

## TIMELESS ILLUMINATING MAKEUP SPF 30 PURE BEIGE MERLE NORMAN

octinoxate, oxybenzone cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:57627-183 |
| <b>Route of Administration</b> | 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)                           |
| TRIETHOXYCAPRYLYLSILANE (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:57627-183-02 | 1 in 1 CARTON  | 01/24/2017           |                    |
| 1         | NDC:57627-183-01 | 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(57627-183) |

