

**TIMELESS AGE DEFYING SPF 20 MERLE NORMAN- octinoxate, oxybenzone cream**  
**Merle Norman**

*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 Age-Defying Makeup SPF 20**

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 product is 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 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 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: Ask a doctor

**Inactive ingredients:** Water (Aqua), Titanium Dioxide, Butylene Glycol, Octldodecyl Neopentanoate, Cyclopentasiloxane, Isodecyl Neopentanoate, Iron Oxides, Stearic Acid, Phenyl Trimethicone, Propylene Glycol Stearate SE, Squalane, Triethanolamine, Dipalmitoyl Hydroxyproline, Trilaurin, Ceramide 3, Hyaluronic Acid, Glycine Soja, ( Soybean) Seed Extract, Atelocollagen, Sodium Hyaluronate, Palmitoyl Oligopeptide, Ascorbyl Palmitate, Tocopheryl Acetate, Propylene Glycol Dipelargonate, Ethylene/ Acrylic Acid Copolymer, Panthenol, Allantoin, Lecithin, Glyceryl Polymethacrylate, Dimethionol, Cetyl Phosphate, Tricaprylin, Mica ( CI 77019), Stearyl Alcohol, PEG-8, Cellulose gum, PEG-12 Dimethicone, Silica, Polyquaternium-24, Sodium Chondroitin Sulfate, Magnesium Aluminum Silicate, Carbomer, Polysorbate 20, Tetrasodium EDTA, Disodium EDTA, Diazolidinyl Urea, BHT, Ethylene Dodecanedioate Phenoxyethanol

Timeless

Age-Defying Makeup SPF 20

Merle Norman

30 mL 1 FL. OZ.

664A

**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, Titanium Dioxide (CI 77891), Butylene Glycol, Octyldodecyl Neopentanoate, Cyclopentasiloxane, Isodecyl Neopentanoate, Iron Oxides (CI 77489, CI 77491, CI 77492, CI 77499), Stearic Acid, Phenyl Trimethicone, Propylene Glycol Stearate SE, Squalane, Triethanolamine, Dipalmitoyl Hydroxyproline, Trilaurin, Ceramide NP, Hyaluronic Acid, Glycine Soja (Soybean) Seed Extract, Atelocollagen, Sodium Hyaluronate, Palmitoyl Hexapeptide-12, Ascorbyl Palmitate, Tocopheryl Acetate, Propylene Glycol Dipalargonate, Ethylene/Acrylic Acid Copolymer, Panthenol, Allantoin, Lecithin, Glyceryl Polymethacrylate, Dimethiconol, Cetyl Phosphate, Tricaprylin, Mica (CI 77019), Stearyl Alcohol, PEG-8, Cellulose Gum, PEG-12 Dimethicone, Silica, Polyquaternium-24, Sodium Chondroitin Sulfate, Magnesium Aluminum Silicate, Carbomer, Polysorbate 20, Tetrasodium EDTA, Disodium EDTA, Diazolidinyl Urea, BHT, Ethylene Dodecanedioate, Phenoxyethanol.

**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. Non-comedogenic.  
Testé par un dermatologue. Sans parfum.  
Sans huile. Non comédogène.



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FPO  
ALABASTER BEIGEMERLE NORMAN  
WWW.MERLENORMAN.COM

**TIMELESS  
AGE-DEFYING  
MAKEUP  
BROAD SPECTRUM  
SPF 20**

**MAQUILLAGE RAJEUNISSANT  
LARGE SPECTRE FPS 20**

MERLE NORMAN

ESTABLISHED IN LOS ANGELES  
SINCE 1931

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

EMULSION/ÉMULSION  
DIN O2245985

**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.

**Avvertissements****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

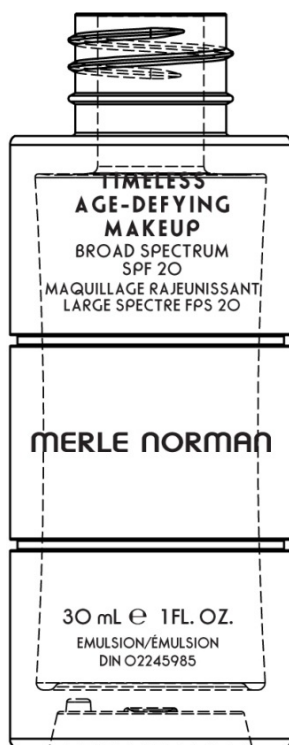
**Ne pas laisser à la portée des enfants.** Si vous avez ce produit, consultez un médecin ou contactez immédiatement un centre antipoison. ▶



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

O17-99-42  
R-O

5pt



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  
AGE-DEFYING  
MAKEUP**  
BROAD SPECTRUM  
SPF 20  
MAQUILLAGE RAJEUNISSANT  
LARGE SPECTRE FPS 20

**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. **Ne pas laisser à la portée des enfants.** Si vous avalez ce

MERLE NORMAN

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

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



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



30 mL e 1FL. OZ.  
EMULSION/EMULSION  
DIN 02245985

## TIMELESS AGE DEFYING SPF 20 MERLE NORMAN

octinoxate, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57627-115
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 g in 30 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	.6 g in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
FERROUS OXIDE (UNII: G7036X8B5H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SQUALANE (UNII: GW89575KF9)
TROLAMINE (UNII: 9O3K93S3TK)
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)
TRILAURIN (UNII: 7FP2Z3RVUV)
CERAMIDE 3 (UNII: 4370DF050B)
HYALURONIC ACID (UNII: S270N0TRQY)
SOYBEAN (UNII: L7HT8FIZOD)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
PANTHENOL (UNII: WV9CM0O67Z)
ALLANTOIN (UNII: 344S277G0Z)
CETYL PHOSPHATE (UNII: VT07D6X67O)
TRICAPRYLIN (UNII: 6P92858988)
MICA (UNII: V8A1AW0880)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
EDETATE SODIUM (UNII: MP1J8420LU)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-115-02	1 in 1 BOX	05/05/2011	
1	NDC:57627-115-01	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	05/05/2011	

**Labeler** - Merle Norman (008479388)

**Registrant** - Merle Norman (008479388)

### Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman		008479388	manufacture(57627-115)

