

IVORY PERFECTING MAKEUP BROAD SPECTRUM SPF 25 MERLE NORMAN- octinoxate, titanium dioxide emulsion

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.

Ivory Perfecting Makeup SPF 25

Active Ingredients purpose

Octinoxate 7.5% Sunscreen

Titanium Dioxide 7.1% 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 and persists

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 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- 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), Cyclopentasiloxane, Cyclohexasiloxane, Isododecane, Alcohol Denat., Cetyl PEG/PPG-10/1 Dimethicone, C12-15 Alkyl Benzoate, Acrylates/Dimethicone Copolymer, Silica, Acrylates Copolymer, Sodium Myristoyl Glutamate, Sorbitan Sesquioleate, Polyhydroxystearic Acid, Disteardimonium Hectorite, Caprylyl Glycol, Aluminum Oxide, Stearic Acid, Propylene Glycol, Propylene Carbonate, Tetrasodium EDTA, Methylisothiazolinone,
May Contain: Iron Oxides, Titanium Dioxide, Triethoxycaprylylsilane

662

DERMATOLOGIST TESTED.
OIL-FREE. FRAGRANCE-FREE.
NON-COMEDOGENIC.
SHAKE WELL. APPLY WITH
BRUSH, SPONGE OR FINGERTIPS.

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Titanium Dioxide 7.1%	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.

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 and persists.

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

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 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 of age: Ask a doctor.

Drug Facts (continued)

Inactive Ingredients

Water (Aqua), Cyclopentasiloxane, Cyclohexasiloxane, Isododecane, Alcohol Denat., Cetyl PEG/PPG-10/1 Dimethicone, C12-15 Alkyl Benzoate, Acrylates/Dimethicone Copolymer, Silica, Acrylates Copolymer, Sodium Myristoyl Glutamate, Sorbitan Sesquileate, Polyhydroxystearic Acid, Disteardimonium Hectorite, Caprylyl Glycol, Aluminum Oxide, Stearic Acid, Propylene Glycol, Propylene Carbonate, Tetrasodium EDTA, Methylisothiazolinone, May Contain: Iron Oxides, Titanium Dioxide, Triethoxycaprylylsilane Q22212.

Other information

Protect the product in this container from excessive heat and direct sun.

Questions & comments?

1-800-421-2060 9:00 am to 5:00 pm pst



MERLE NORMAN
WWW.MERLENORMAN.COM

PERFECTING
MAKEUP
BROAD SPECTRUM
SPF 25

MERLE NORMAN
ESTABLISHED IN LOS ANGELES
SINCE 1931

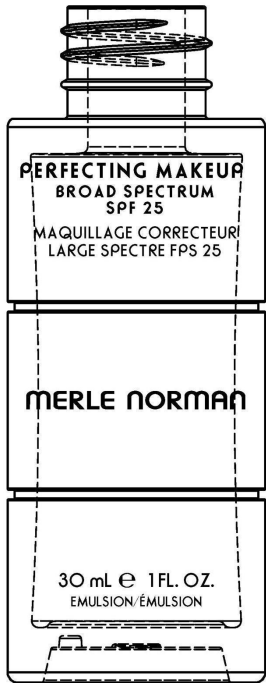
30 mL e
1 FL.OZ.



MANUFACTURED BY:
MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN USA

PRINTED
IN U.S.A.

016-98-40
R-O



DERMATOLOGIST TESTED.
TESTÉ PAR UN DERMATOLOGUE.
Directions: Shake well. Apply prior to sun exposure.
Mode d'emploi: Agitez bien. Appliquez avant de vous mettre au soleil.

Warnings: For external use only. Not to be swallowed. Avoid contact with eyes. Stop use and ask a doctor if rash or irritation develops or lasts. Keep out of reach of children.
Avertissement: Pour usage externe uniquement. Ne pas avaler. Éviter le contact avec les yeux. Arrêter l'utilisation et consulter votre médecin si une éruption ou une irritation se développe ou dure. Ne pas laisser à la portée des enfants.

Active (Medicinal) Ingredients (w/w): Octinoxate 7.5%, Titanium Dioxide 7.1%.

MANUFACTURED BY: MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN U.S. OF U.S. AND IMPORTED PARTS.
IMPORTED BY: MERLE NORMAN COSMETICS
TORONTO, ONTARIO M1X 1E7

PERFECTING MAKEUP
BROAD SPECTRUM
SPF 25
MAQUILLAGE CORRECTEUR
LARGE SPECTRE FPS 25

MERLE NORMAN

30 mL e 1FL. OZ.
EMULSION / ÉMULSION

Perfecting Makeup Broad Spectrum SPF 25
Merle Norman Established in Los Angeles since 1931
30 mL 1 Fl. Oz.

IVORY PERFECTING MAKEUP BROAD SPECTRUM SPF 25 MERLE NORMAN

octinoxate, titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 g in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.13 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ISODODECANE (UNII: A8289P68Y2)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM MYRISTOYL GLUTAMATE (UNII: AYU7QD893W)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	

POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALUMINUM OXIDE (UNII: LM26O6933)
STEARIC ACID (UNII: 4ELV7Z65AP)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
EDETATE DISODIUM (UNII: 7FLD91C86K)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-125-02	1 in 1 CARTON	08/22/2012	
1	NDC:57627-125-01	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 not final	part352	08/22/2012	

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(57627-125)