

FLAWLESS EFFECT LIQUID FOUNDATION SPF 15 MERLE NORMAN- octinoxate, oxybenzone liquid
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.

Merle Norman Flawless Effect Liquid Foundation SPF 15

Active Ingredients

Octinoxate 7.50%

Oxybenzone 3.00%

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:

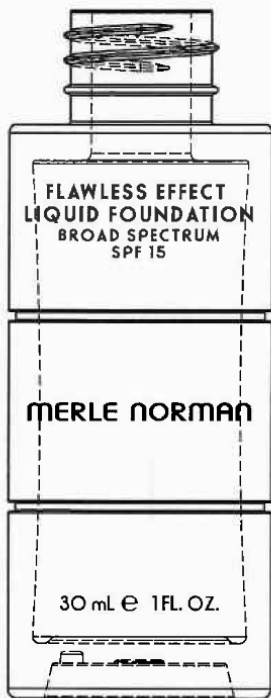
- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with 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

Water(aqua), cyclopentasiloxane , mica, titanium dioxide, diisostearyl malate, ethylhexyl palmitate, glycerin, pentyleneglycol, peg-30 dipolyhydroxystearate, iron oxides, propylene glycol, cyclohexasiloxane, aluminum starch octenylsuccinate, disteardimonium hectorite, hdi/ppg/polycaprolactone crosspolymer, glyceryl oleate, glyceryl stearate, myristyl myristate, polyglyceryl-3 beeswax, lecithin, disodium stearyl glutamate, Butylene Glycol, sodium hyaluronate, camellia oleifera leaf extract, ginkgo biloba leaf extract, chamomilla recutita (matricaria) flower extract, tetrahexyldecyl ascorbate, tocopheryl acetate, aluminum hydroxide (CI 77002), silica, alcohol denat., BHT, phenoxyethanol, methylparaben, propylparaben

Flawless Effect Liquid Foundation SPF 15

Merle Norman

30 mL 1 FL. OZ.



DERMATOLOGIST TESTED.
DIRECTIONS: SHAKE WELL, APPLY PRIOR TO SUN EXPOSURE.

WARNINGS: FOR EXTERNAL USE ONLY. DO NOT SWALLOW. AVOID CONTACT WITH EYES. STOP USE IF IRRITATION OCCURS. KEEP OUT OF REACH OF CHILDREN.

ACTIVE INGREDIENTS: OCTINOXATE 7.50%, OXYBENZONE 3.00%.

 
MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN U.S. OF U.S. AND IMPORTED PARTS

FLAWLESS EFFECT
LIQUID FOUNDATION
BROAD SPECTRUM
SPF 15

MERLE NORMAN

30 mL e 1FL. OZ.

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Drug Facts (continued)

Inactive Ingredients

Water (Aqua), Cyclopentasiloxane, Mica, Titanium Dioxide, Disostearyl Malate, Ethylhexyl Palmitate, Glycerin, Pentylene Glycol, PEG-30 Dipolyhydroxystearate, Iron Oxides, Propylene Glycol, Cyclohexasiloxane, Aluminum Starch Octenylsuccinate, Distearidimonium Hectorite, HDI/PPG/Polycaprolactone Crosspolymer, Glyceryl Oleate, Glyceryl Stearate, Myristyl Myristate, Polyglyceryl-3 Beeswax, Lecithin, Disodium Stearoyl Glutamate, Butylene Glycol, Sodium Hyaluronate, Camellia Oleifera Leaf Extract, Ginkgo Biloba Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Aluminum Hydroxide, Silica, Alcohol Denat., BHT, Phenoxethanol, Methylparaben, Propylparaben 071509.

Other information

DERMATOLOGIST TESTED.
OIL-FREE. FRAGRANCE-FREE.
NON-ACNEGENIC.
NON-COMEDOGENIC.

APPLY WITH BRUSH,
SPONGE OR FINGERTIPS.

**FLAWLESS EFFECT
LIQUID
FOUNDATION
BROAD SPECTRUM
SPF 15**

MERLE NORMAN
ESTABLISHED IN LOS ANGELES

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Oxybenzone 3.0%	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.

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use:



FLAWLESS EFFECT LIQUID FOUNDATION SPF 15 MERLE NORMAN

octinoxate, oxybenzone liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-113
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)		OXYBENZONE	0.9 g in 30 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	2.25 g in 30 g
Inactive Ingredients			
Ingredient Name			Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
MICA (UNII: V8A1AW0880)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
ETHYLHEXYL PALMITATE (UNII: 2865993309)			
GLYCERIN (UNII: PDC6A3C0OX)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			

PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
FERROUS OXIDE (UNII: G7036X8B5H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
GLYCERYL 1-OLEATE (UNII: D3AEF6S35P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
GINKGO (UNII: 19FUJ2C58T)	
CHAMOMILE (UNII: FGL3685T2X)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-113-02	1 in 1 CARTON	04/25/2011	
1	NDC:57627-113-01	30 g 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	04/25/2011	

Labeler - Merle Norman (008479388)

Registrant - Merle Norman (008479388)

Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman		008479388	manufacture(57627-113)