

SHEER DEFENSE TINTED MOISTURIZER SPF 15 L10 MERLE NORMAN- octinoxate, titanium dioxide liquid

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.

Sheer Defense Tinted Moisturizer Broad Spectrum SPF 15 L10

Active Ingredients Purpose

Octinoxate 7.5% Sunscreen

Dioxide 5.12% 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, 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-sleeve shirts, pants, hats, and sunglasses

Children under 6 months: Ask a doctor

Water (Aqua), Dimethicone, Butylene Glycol, Glyceryl Stearate SE, Mica, Talc, Iron Oxides, Glyceryl Dilaurate, Glyceryl Behenate, Ceramide 3, Saccharide Isomerate, Allantoin, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Glycine Soja (Soybean) Germ Extract, Echinacea Purpurea Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Equisetum Arvense Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Camellia Oleifera Leaf Extract, Lecithin, Petrolatum, Palmitic Acid, Polyglyceryl-10 Decaoleate, Polyacrylamide, PEG-12 Dimethicone, octyldodecyl Stearoyl Stearate, Steareth-20, C13-14 Isoparaffin, Isocetyl Alcohol, Propylene Glycol, Laureth-7, Silica, Cyclodextrin, Disodium EDTA, Phenoxyethanol, Tetrasodium

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Drug Facts (continued)

Inactive ingredients:

Water (Aqua), Dimethicone, Butylene Glycol, Glyceryl Stearate SE, Mica, Talc, Iron Oxides, Glyceryl Dilaurate, Glyceryl Behenate, Ceramide 3, Saccharide Isomerate, Allantoin, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Glycine Soja (Soybean) Germ Extract, Echinacea Purpurea Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Equisetum Arvense Extract, Chamomilla Recutita (Matricaria) Flower Extract, Cucumis Sativus (Cucumber) Fruit Extract, Camellia Oleifera Leaf Extract, Lecithin, Petrolatum, Palmitic Acid, Polyglyceryl-10 Decaoleate, Polyacrylamide, PEG-12 Dimethicone, octyldodecyl Stearoyl Stearate, Steareth-20, C13-14 Isoparaffin, Isocetyl Alcohol, Propylene Glycol, Laureth-7, Silica, Cyclodextrin, Disodium EDTA, Phenoxyethanol, Tetrasodium EDTA, BHT, Diazolidinyl Urea, Fragrance (Parfum) 101608.

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

 
 MERLE NORMAN COSMETICS
 LOS ANGELES, CA 90045
 MADE IN USA

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

APPLY WITH BRUSH,
 SPONGE OR
 FINGERTIPS.

**SHEER DEFENSE
 TINTED MOISTURIZER
 BROAD SPECTRUM
 SPF 15**

L10

MERLE NORMAN
 ESTABLISHED IN LOS ANGELES
 SINCE 1931

35 g e
 NET WT. 1.25 OZ.



PRINTED
 IN U.S.A.

L10



MERLE NORMAN
 WWW.MERLENORMAN.COM

Drug Facts

Active ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Titanium Dioxide 5.12%	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

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Stop use and ask a doctor if rash occurs

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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

007-57-42
 R-O



Sheer Defense Tinted Moisturizer Broad Spectrum SPF 15

L10

Merle Norman

Established in Los Angeles since 1931

35 g Net Wt. 1.25 oz

SHEER DEFENSE TINTED MOISTURIZER SPF 15 L10 MERLE NORMAN

octinoxate, titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-151
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 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	5.12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
MICA (UNII: V8A1AW0880)
TALC (UNII: 7SEV7J4R1U)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)
CERAMIDE 3 (UNII: 4370DF050B)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
ALLANTOIN (UNII: 344S277G0Z)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
SOYBEAN GERM (UNII: JBW2VHD14M)
ECHINACEA PURPUREA (UNII: QI7G114Y98)
FENNEL SEED (UNII: G3QC02NIE6)
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)
CHAMOMILE (UNII: FGL3685T2X)
CUCUMBER (UNII: YY7C30VXJT)
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PETROLATUM (UNII: 4T6H12BN9U)
PALMITIC ACID (UNII: 2V16EO95HI)
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)
STEARETH-20 (UNII: L0Q8IK9E08)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
ISOCETYL ALCOHOL (UNII: 1800H64066)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
LAURETH-7 (UNII: Z95S6G8201)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE SODIUM (UNII: MP1J8420LU)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-151-02	1 in 1 CARTON	12/06/2012	
1	NDC:57627-151-01	35 g in 1 TUBE; 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	12/06/2012	

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(57627-151)

Revised: 1/2020

Merle Norman Cosmetics, Inc.