SHEER DEFENSE TINTED MOISTURIZER SPF15 L20 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 L20

Active ingredients Purpose

Octinoxate 7.5% Sunscreen

Titanium Dioxide 5.02% 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

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)



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



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

APPLY WITH BRUSH, SPONGE OR FINGERTIPS. SHEER DEFENSE TINTED MOISTURIZER BROAD SPECTRUM SPF 15

L20

MERLE NORMAN

ESTABLISHED IN LOS ANGELES SINCE 1931

35 g € NET WT. 1.25 OZ.

Drug Facts

Active ingredients

Octinoxate 7.5% Titanium

ate 7.5% Sunscreen

Purpose

Dioxide 5.02% 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

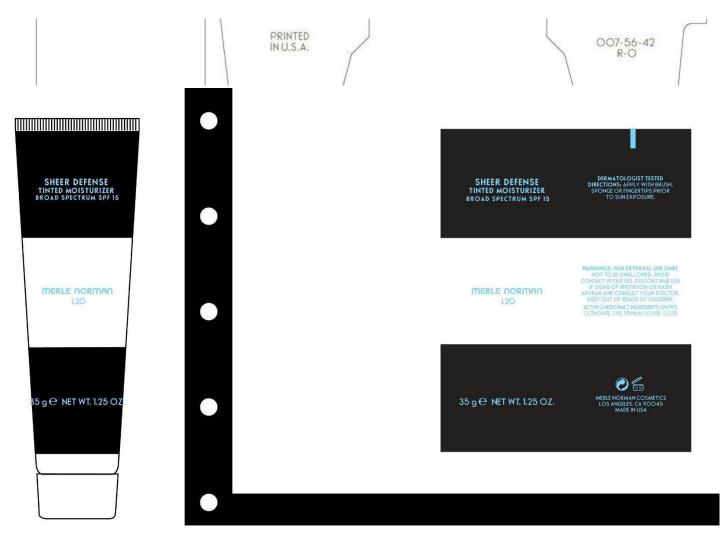
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use:
- apply liberally 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.
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- children under 6 months: Ask a doctor



MERLE NORMAN COSMETICS LOS ANGELES, CA 90045 MADE IN USA



Sheer Defense Tinted Moisturizer Broad Spectrum SPF 15

L20

Merle Norman

Established in Los Angeles since 1931

35 g Net wt. 1.25 Oz.

SHEER DEFENSE TINTED MOISTURIZER SPF15 L20 MERLE NORMAN

octinoxate, titanium dioxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-152
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 DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.02 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
GLYCERYL MO NO BEHENATE (UNII: A6 26 UU0 W2A)	
CERAMIDE 3 (UNII: 4370 DF050B)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
ALLANTO IN (UNII: 344S277G0Z)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
SO YBEAN GERM (UNII: JBW2VHD14M)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
FENNEL SEED (UNII: G3QC02NIE6)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0 VKZ185E)	
CHAMO MILE (UNII: FGL3685T2X)	
CUCUMBER (UNII: YY7C30VXJT)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
PETROLATUM (UNII: 4T6H12BN9U)	
PALMITIC ACID (UNII: 2V16EO95H1)	
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 DIO XIDE (UNII: ETJ7Z6 XBU4)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-152-02	1 in 1 CARTON	12/07/2012	
1	NDC:57627-152-01	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	12/07/2012	

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(57627-152)	

Revised: 1/2020 Merle Norman Cosmetics, Inc.