

VIRTUAL MATTE OIL CONTROL MAKEUP BROAD SPECTRUM SPF 15- octinoxate and titanium dioxide liquid
PRESCRIPTIVES 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.

VIRTUAL MATTE
OIL CONTROL MAKEUP BROAD SPECTRUM SPF 15

Drug Facts

Active ingredients

Octinoxate 2.50%
Titanium Dioxide 0.97%

Purpose

Sunscreen

Use

helps prevent sunburn

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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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 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

Inactive ingredients

water/aqua/eau • cyclopentasiloxane • butylene glycol • peg-10 dimethicone • trimethylsiloxysilicate • dimethicone • magnesium sulfate • dimethicone/peg-10/15 crosspolymer • laminaria saccharina extract • algae extract • acetyl hexapeptide-8 • sodium hyaluronate • cholesterol • ceramide 2 • linoleic acid • tocopheryl • acetate • hydrogenated lecithin • sorbitan sesquioleate • polysilicone-11 • phenyl

trimethicone • lecithin • peg/ppg-18/ 18 dimethicone • disteardimonium hectorite • triethoxycaprylylsilane • propylene carbonate • silica • dimethicone/peg-10 crosspolymer • xanthan gum • laureth-7 • methyl methacrylate crosspolymer • methoxy amodimethicone/ silsesquioxane copolymer • dipropylene glycol • bht • chloroxylenol • phenoxyethanol • methylparaben • propylparaben • [+/- mica • iron oxides (ci 77491, ci 77492, ci 77499) • titanium dioxide (ci 77891)] <ILN37462>

Other information

protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

PRESCRIPTIVES

Virtual Matte

Oil-Control Makeup

Broad Spectrum SPF 15

1 FL. OZ./OZ. LIQ./30 ml e

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Virtual Matte

Oil-Control Makeup

Broad Spectrum SPF 15

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UPC
F.P.O.

Oil-Control Makeup
Satin Matte Finish
Medium to Full Coverage
Broad Spectrum SPF 15

Oil-free foundation — modernized, Oil-control complex with botanical extract absorbs surface shine and when used daily, actually helps reduce excess oil. Broad Spectrum SPF 15 helps protect against environmental damage. Fresh, satin-matte finish.

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Drug Facts (continued)

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Drug Facts (continued)

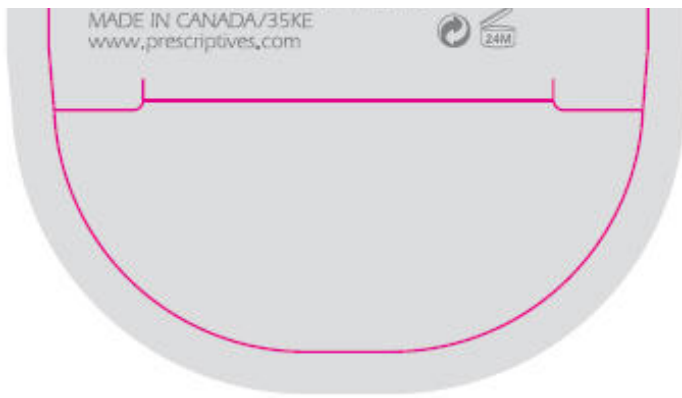
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35KE-01-1112

C150482



VIRTUAL MATTE OIL CONTROL MAKEUP BROAD SPECTRUM SPF 15

octinoxate and titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59158-915
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.02775 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.010767 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
butylene glycol (UNII: 3XUS85K0RA)	
dimethicone (UNII: 92RU3N3Y1O)	
magnesium sulfate (UNII: DE08037SAB)	
saccharina latissima (UNII: 68CMP2MB55)	
acetyl hexapeptide-8 (UNII: L4EL31FWIL)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
cholesterol (UNII: 97C5T2UQ7J)	
ceramide 2 (UNII: C04977SRJ5)	
linoleic acid (UNII: 9KJL21T0QJ)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
sorbitan sesquioleate (UNII: 0W8RRI5W5A)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
peg/ppg-18/18 dimethicone (UNII: 9H0AO7T794)	
disteardimonium hectorite (UNII: X687XDK09L)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
xanthan gum (UNII: TTV12P4NEE)	
laureth-7 (UNII: Z95S6G8201)	

dipropylene glycol (UNII: E107L85C40)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
chloroxylenol (UNII: 0F32U78V2Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
mica (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59 158-9 15-01	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/01/2003	

Labeler - PRESCRIPTIVES INC (151701588)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(59 158-9 15) , REPACK(59 158-9 15)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(59 158-9 15) , RELABEL(59 158-9 15) , REPACK(59 158-9 15)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(59 158-9 15) , RELABEL(59 158-9 15)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59 158-9 15)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(59 158-9 15)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(59158-915) , RELABEL(59158-915) , REPACK(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(59158-915) , RELABEL(59158-915) , REPACK(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(59158-915) , RELABEL(59158-915) , REPACK(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(59158-915)

Establishment			
Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	RELABEL(59158-915) , REPACK(59158-915)