

MINERAL TINTED MOISTURE BROAD SPECTRUM SPF 15 OIL FREE- titanium dioxide lotion

AVEDA COPORATION

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.

**MINERAL TINTED MOISTURE
BROAD SPECTRUM SPF 15 OIL FREE LOTION**

Drug Facts

Active Ingredient

Titanium Dioxide 4.3%

Purpose

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 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.

Directions

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, Tricaprylyl Citrate, Phenyl Trimethicone, Jojoba Esters, Hydrogenated Lecithin,

Glyceryl Stearate, PEG-100 Stearate, Glycerin, Magnesium Aluminum Silicate, Cetyl Alcohol, Glyceryl Caprylate, Capryloyl Glycine, Salix Nigra (Willow) Bark Extract, Polygonum Cuspidatum Root Extract, Tourmaline, Decyl Glucoside, Sodium Lauroyl Lactylate, Dipotassium Glycyrrhizate, Xanthan Gum, Fragrance (Parfum), Aluminum Hydroxide, Disodium Coco-Glucoside Citrate, Sodium Gluconate, Citric Acid, [+/- Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499), Mica] <ILN36354>

Other Information

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

Aveda Corp., Dist., Minneapolis,
MN 55449

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

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THE ART AND SCIENCE OF PURE
FLOWER AND PLANT ESSENCES

INNER LIGHT™

mineral tinted moisture
broad spectrum spf 15
OIL-FREE LOTION

1.7 fl oz/50 ml e

Drug Facts (continued)

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THE ART AND SCIENCE OF PURE
FLOWER AND PLANT ESSENCES



INNER LIGHT™

mineral tinted moisture
broad spectrum spf 15
OIL-FREE LOTION

1.7 fl oz/oz liq/50 ml e

Drug Facts

Active Ingredient

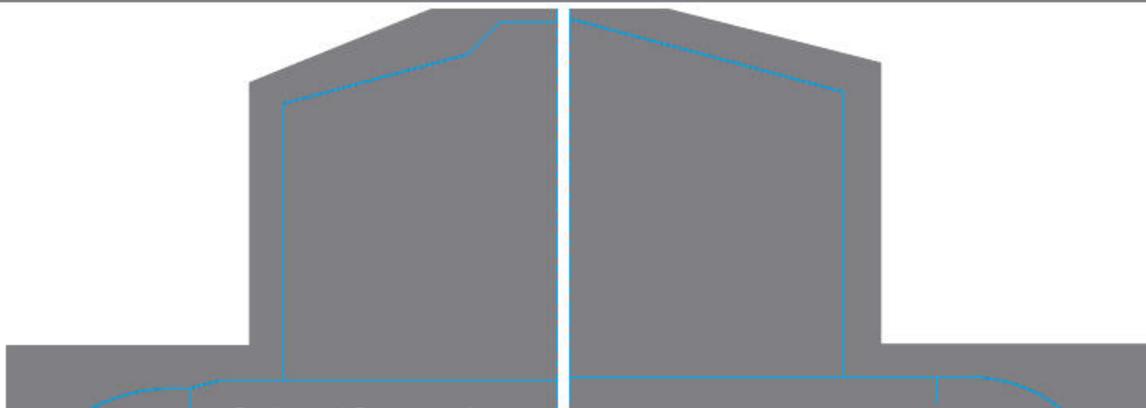
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MINERAL TINTED MOISTURE BROAD SPECTRUM SPF 15 OIL FREE

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57677-059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	0.04601 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Tricaprylyl Citrate (UNII: BXW1GAI4TA)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glycerin (UNII: PDC6A3C0OX)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glyceryl Caprylate (UNII: TM2TZD4G4A)	
Capryloyl Glycine (UNII: 8TY5YO42NJ)	
Salix Nigra Bark (UNII: QU52J3A5B3)	
Polygonum Cuspidatum Root (UNII: 7TRV45YZF7)	
Decyl Glucoside (UNII: Z17H97EA6Y)	

Sodium Lauroyl Lactylate (UNII: 7243K85WFO)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Xanthan Gum (UNII: TTV12P4NEE)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Sodium Gluconate (UNII: R6Q3791S76)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Mica (UNII: V8A1AW0880)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57677-059-01	1 in 1 CARTON		
1		50 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2012	

Labeler - AVEDA COPORATION(071352058)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(57677-059) , REPACK(57677-059)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(57677-059) , RELABEL(57677-059) , REPACK(57677-059)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(57677-059)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(57677-059) , RELABEL(57677-059)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(57677-059) , RELABEL(57677-059) , REPACK(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(57677-059) , RELABEL(57677-059) , REPACK(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(57677-059) , RELABEL(57677-059) , REPACK(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(57677-059)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(57677-059) , RELABEL(57677-059)