OIL CLEARING MATTE MOISTURIZER- avobenzone, octinoxate, oxybenzone, and octis alate lotion

Dermalogica, 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.

Oil Clearing Matte Moisturizer

Drug Facts

Active ingredients

Avobenzone (2.5%), Octinoxate (6.0%), Octisalate (5.0%), Oxybenzone (4.0%).

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), helps decrease 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 physician

if rash occurs

Keep out of reach of children.

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

Directions

- Apply liberally 30 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 help decrease this risk, regularly use a sunscreen with a 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.

Other information

• Protect this product from excessive heat and direct sun.

Inactive ingredients

Water/Aqua/Eau, Butylene Glycol, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Silica, Dimethyl Capramide, Citrus Aurantium Dulcis (Orange) Peel Oil, Cariandrum Sativum (Coriander) Fruit Oil, Citrus Aurantifolia (Lime) Peel Oil, Citrus Aurantium Amara (Bitter Orange) Peel Oil, Citrus Aurantium Dulcis (Orange) Flower Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Medica Limonum (Lemon) Peel Oil, Elettaria Cardamomum Seed Oil, Eucalyptus Globulus Leaf Oil, Eugenia Caryophyllus (Clove) Leaf Oil, Lavandula Hybrida Oil, Salvia Sclarea (Clary) Oil, Zingiber Officinale (Ginger) Root Oil, Enantia Chlorantha Bark Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Betula Alba Bark Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Salix Alba (Willow) Bark Extract, Oleanolic Acid, Tocopherol, Cetearyl Phosphate, Stearic Acid, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer, Nylon-12, Xanthan Gum, Cetyl Alcohol, Aminomethyl Propanol, Sodium Benzoate, Disodium EDTA, Phenoxyethanol, Ethylhexylglycerin, Titanium Dioxide (CI 77891).

Questions or comments

Call toll free 1-800-831-5150 in the US

PRINCIPAL DISPLAY PANEL - 59 mL Tube Carton

dermalogica® clear

spf 15 broad spectrum

Oil Clearing

Matte Moisturizer

2.0 US FL OZ / 59 mL e

Oil Clearing

Matte

Moisturizer

oiliness

spf





Oil Clearing

Matte Moisturizer

2.0 US FL OZ / 59 mL @

Clear Start is created by Dermalogica, the #1 professional skin care brand worldwide, to treat younger, breakoutprone skin.

Oil Clearing

Matte Moisturizer



All-day shine control step 3: use daily, a.m.

A moisturizer that minimizes oil and shine? It's true! This ultra-light, non-greasy hydrating formula controls oily areas like the nose and forehead for an all-over matte finish. SPF helps shield against the UV rays that can make breakouts worse and cause dark spots.

Clear Start™ is tough on breakouts, gentle on your skin: potent active ingredients and

Drug Facts

(continued)

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- Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To help decrease this risk, regularly use a sunscreen with a broad naturally gentle botanicals deliver your clearest, healthiest skin ever.

- Special botanical oil-absorbers act like micro sponges to minimize shine, while moisturizers keep skin hydrated.
- Formulated with 19 gentle botanicals including Licorice, Birch and Willow, known to soothe and protect skin.
- Broad Spectrum sunscreens provide critical defense against UVA and UVB rays without clogging pores and causing breakouts.

We don't formulate with artificial fragrances, dyes or mineral oils. Get more great skin tips at clearstart.com.

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Questions or comments

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clearstart.com

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OIL CLEARING MATTE MOISTURIZER

avobenzone, octinoxate, oxybenzone, and octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	25 mg in 1 mL	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	60 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL	
Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	50 mg in 1 mL	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Dimethyl Capramide (UNII: O29 Y6 X2JEZ)	
Orange Oil (UNII: AKN3KSD11B)	
Coriander Oil (UNII: 7626GC95E5)	
Citrus Aurantiifolia Seed Oil (UNII: EW089HAI77)	
Bitter Orange Oil (UNII: 9TLV70SV6I)	
Citrus Sinensis Flower Oil (UNII: AJ56JP5TFP)	
Citrus Maxima Fruit Rind Oil (UNII: 8U3877WD44)	
Lemon Oil (UNII: 19 GRO 824LL)	
Cardamom Oil (UNII: JM0 KJ09 1HZ)	
Eucalyptus Oil (UNII: 2R04ONI662)	
Clove Leaf Oil (UNII: VCA5491KVF)	
Lavandin Oil (UNII: 9RES347CKG)	
Clary Sage Oil (UNII: 87L0D4U3M0)	
Ginger Oil (UNII: SAS9Z1SVUK)	
Annickia Chlorantha Bark (UNII: H70115MP4A)	
Arctium Lappa Root (UNII: 597E9BI3Z3)	
Arnica Montana Flower (UNII: OZ0E5Y15PZ)	
Betula Pubescens Bark (UNII: 3R504894L9)	
Glycyrrhiza Glabra (UNII: 2788Z9758H)	
Salix Alba Bark (UNII: 205MXS71H7)	
Oleanolic Acid (UNII: 6SMK8R7TGJ)	
Tocopherol (UNII: R0ZB2556P8)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Nylon-12 (UNII: 446 U8 J0 75 B)	
Xanthan Gum (UNII: TTV12P4NEE)	
Cetyl Alcohol (UNII: 936JST6JCN)	

Sodium Benzoate (UNII: OJ245FE5EU)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-140-02	1 in 1 CARTON		
1		59 mL in 1 TUBE		
2	NDC:68479-140-01	14 mL in 1 TUBE		
3	NDC:68479-140-00	2 mL in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/29/2013	

Labeler - Dermalogica, Inc. (177698560)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosway		620899877	MANUFACTURE(68479-140)	

Establishment			
Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 110 4729	MANUFACTURE(68479-140)

Revised: 2/2014 Dermalogica, Inc.