

ULTRASENSITIVE TINT SPF 30- titanium dioxide 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.

UltraSensitive Tint

SPF 30

Drug Facts

Active Ingredient

Titanium Dioxide 11.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), may 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 Doctor if rash occurs.

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

Do not use if seal is broken.

Directions

- 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 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

Inactive ingredients

Water/Aqua, Butylene Glycol, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Caprylic/Capric

Triglyceride, Neopentyl Glycol Diethylhexanoate, Arachidyl Alcohol, PEG-10 Dimethicone, Dimethicone, Behenyl Alcohol, Leuconostoc/Radish Root Ferment Filtrate, Stearyl Dimethicone, Potassium Cetyl Phosphate, Camellia Oleifera Leaf Extract, Avena Sativa (Oat) Kernel Extract, Boerhavia Diffusa Root Extract, Melissa Officinalis Extract, Vitis Vinifera (Grape) Seed Extract, Citrus Medica Limonum (Lemon) Peel Extract, Centella Asiatica Extract, Echinacea Purpurea Extract, Zingiber Officinale (Ginger) Root Extract, Citrus Grandis (Grapefruit) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Thymus Vulgaris (Thyme) Oil, Pelargonium Graveolens Oil, Aniba Rosaeodora (Rosewood) Wood Oil, Citrus Aurantium Dulcis (Orange) Oil, Bisabolol, Tocopherol, Lecithin, Panthenol, Sodium Lactate, Sodium PCA, Sorbitol, Proline, Pentylene Glycol, Hydroxyphenyl Propamidobenzoic Acid, Glycerin, Magnesium Ascorbyl Phosphate, Silica, Arachidyl Glucoside, Cetearyl Alcohol, Cetareth-20, Sodium DNA, Ascorbyl Tetraisopalmitate, Neopentyl Glycol Diisostearate, Alumina, Methicone, Stearic Acid, Aluminum Hydroxide, Polyglyceryl-2 Dipolyhydroxy Stearate, Polyglyceryl-3 Diisostearate, Xanthan Gum, Magnesium Aluminum Silicate, Carbomer, Disodium EDTA, Sodium Benzoate, Potassium Sorbate, Sodium Hydroxide, Iron Oxides (77491, 77492, 77499).

Other information

- Protect this product from excessive heat and direct sun

Questions or comments

Call toll free

1-800-831-5150 in the US

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

dermalogica[®]

ultra
sensitive
tint

spf
30

broad
spectrum

NPN# 80031341

UltraCalming[™]

1.7 US Fl. Oz.
50 mL e

ultra
sensitive
tint

ultra
sensitive
tint

spf
30

broad
spectrum

malogica[®]

researched and developed by The International Dermal Institute

Drug Facts (continued)

Inactive ingredients

Water/Aqua, Butylene Glycol, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Neopentyl Glycol Diethylhexanoate, Arachidyl Alcohol, PEG-10 Dimethicone, Dimethicone, Behenyl Alcohol, Leuconostoc/Radish Root Ferment Filtrate, Stearyl Dimethicone, Potassium Cetyl Phosphate, Camellia Oleifera Leaf Extract, Avena Sativa (Oat) Kernel Extract, Boerhavia Diffusa Root Extract, Melissa Officinalis Extract, Vitis Vinifera (Grape) Seed Extract, Citrus Medica Limonum (Lemon) Peel Extract, Centella Asiatica Extract, Echinacea Purpurea Extract, Zingiber Officinale (Ginger) Root Extract, Citrus Grandis (Grapefruit) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Thymus Vulgaris (Thyme) Oil, Pelargonium Graveolens Oil, Aniba Rosaeodora (Rosewood) Wood Oil, Citrus Aurantium Dulcis (Orange) Oil, Bisabolol, Tocopherol, Lecithin, Panthenol, Sodium Lactate, Sodium PCA, Sorbitol, Proline, Pentylene Glycol, Hydroxyphenyl Propamido benzoic Acid, Glycerin, Magnesium Ascorbyl Phosphate, Silica, Arachidyl Glucoside, Cetearyl Alcohol, Cetearth-20, Sodium DNA, Ascorbyl Tetraisopalmitate, Neopentyl Glycol Diisostearate, Alumina, Methicone, Stearic Acid, Aluminum Hydroxide, Polyglyceryl-2 Dipolyhydroxy Stearate, Polyglyceryl-3 Diisostearate, Xanthan Gum, Magnesium Aluminum Silicate, Carbomer, Disodium EDTA, Sodium

NPN# 80031341

UltraCalming™

1.7 US Fl. Oz.

50 mL 

der

a skin care system res

Benzoate, Potassium Sorbate,
Sodium Hydroxide, Iron Oxides
(77491, 77492, 77499).

Other information

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Questions or comments

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1-800-831-5150 in the US

ultra
sensitive
tint



Broad Spectrum sunscreen with tinted earth minerals helps calm sensitized, reactive and recently resurfaced skin. Help guard skin against UV damage with antioxidants from soothing Grape Seed and Green Tea extracts, as physical sunscreens shield against skin-aging and irritating UV damage. Rich formula with natural humectants helps protect against environmental moisture loss, as antioxidant vitamins and botanicals

Drug Facts

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When using this product keep out of eyes. Rinse with water to remove

help guard skin against premature aging and aggravation. Contains our exclusive *UltraCalming™ Complex*. Formulated without artificial fragrances and colors.

Dermatologist tested, Skin Therapist approved. Product guaranteed when professionally recommended. Ask your skin therapist for your free Face Mapping® skin analysis and UltraCalming™ prescription to ensure maximum results.

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Dermalogica, Dist.
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1-800-831-5150
Dermalogica (Canada) Ltd.
Canada: Toronto, ON M5V 2T3



dermalogica®
dermalogica.com

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(D1112-00)

110559-01



ULTRASENSITIVE TINT SPF 30

titanium dioxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68479-120

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	110 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Neopentyl Glycol Diethylhexanoate (UNII: U68ZV6W62C)	
Arachidyl Alcohol (UNII: 1QR1QA9BU)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Dimethicone (UNII: 92RU3N3Y1O)	
Docosanol (UNII: 9G1OE216XY)	
Leuconostoc/Radish Root Ferment Filtrate (UNII: D2QHA03458)	
Stearyl Dimethicone (400 MPA.S at 50 C) (UNII: R327X197HY)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Camellia Oleifera Leaf (UNII: 5077EL0C60)	
Oat (UNII: Z6J799EAJK)	
Boerhavia Diffusa Root (UNII: KR0SR09KYL)	
Melissa Officinalis (UNII: YF70189L0N)	
Vitis Vinifera Seed (UNII: C34U15ICXA)	
Lemon Peel (UNII: 72O054U628)	
Centella Asiatica (UNII: 7M867G6T1U)	
Echinacea Purpurea (UNII: Q17G114Y98)	
Ginger (UNII: C5529G5JPQ)	
Citrus Maxima Fruit Rind Oil (UNII: 8U3877WD44)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Thyme Oil (UNII: 2UK410MY6B)	
Geranium Oil, Algerian Type (UNII: 5Q1I94P4WG)	
Rosewood Oil (UNII: F2522O5L7B)	
Orange Oil (UNII: AKN3KSD11B)	
Levomenol (UNII: 24WE03BX2T)	
Tocopherol (UNII: R0ZB2556P8)	
Egg Phospholipids (UNII: 1Z74184RGV)	
Panthenol (UNII: WV9CM0O67Z)	
Sodium Lactate (UNII: TU7HW0W0QT)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Sorbitol (UNII: 506T60A25R)	
Proline (UNII: 9DLQ4CIU6V)	
Pentylene Glycol (UNII: 50C1307PZG)	
Hydroxyphenyl Propamidobenzoic Acid (UNII: 25KRT26H77)	
Glycerin (UNII: PDC6A3C0OX)	

Magnesium Ascorbyl Phosphate (UNII: 0R822556M5)
Silicon Dioxide (UNII: ETJ7Z6XBU4)
Arachidyl Glucoside (UNII: 6JVVW35JOOJ)
Cetostearyl Alcohol (UNII: 2DMT128M1S)
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)
Ascorbyl Tetraisopalmitate (UNII: 47143LT58A)
Neopentyl Glycol Diisostearate (UNII: 4M6OQ34JWW)
Aluminum Oxide (UNII: LMI26O6933)
Methicone (20 CST) (UNII: 6777U11MKT)
Stearic Acid (UNII: 4ELV7Z65AP)
Aluminum Hydroxide (UNII: 5QB0T2IUN0)
Polyglyceryl-2 Dipolyhydroxystearate (UNII: 9229XJ4V12)
Polyglyceryl-3 Diisostearate (UNII: 46P231IQV8)
Xanthan Gum (UNII: TTV12P4NEE)
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)
Edetate Disodium (UNII: 7FLD91C86K)
Sodium Benzoate (UNII: OJ245FE5EU)
Potassium Sorbate (UNII: 1VPU26JZZ4)
Sodium Hydroxide (UNII: 55X04QC32I)
Ferric Oxide Red (UNII: 1K09F3G675)
Ferric Oxide Yellow (UNII: EX438O2MRT)
Ferrosoferric Oxide (UNII: XM0M87F357)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-120-02	1 in 1 CARTON		
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-120-00	2 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/14/2012	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations

PakLab		790530976	MANUFACTURE(68479-120)
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Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 1104729	MANUFACTURE(68479-120)

Revised: 11/2015

Dermalogica, Inc.