SUPER SENSITIVE SHIELD SPF 30- titanium dioxide and zinc oxide 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.

Super Sensitive Shield SPF 30

Drug Facts

Active Ingredients

Titanium Dioxide 7.0%, Zinc Oxide 9.0%.

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 Doctor 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 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.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Water/Aqua/Eau, Cyclopentasiloxane, Dicaprylyl Ether, Butylene Glycol, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Aluminum Hydroxide, Dimethicone, Leuconostoc/Radish Root Ferment Filtrate, Camellia Sinensis Leaf Extract, Avena Sativa (Oat) Kernel Extract, Boerhavia Diffusa Root Extract, Oxothiazolidine, Citrullus Vulgaris (Watermelon) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Sodium Hyaluronate, Sodium PCA, Sodium Lactate, Lens Esculenta (Lentil) Fruit Extract, Ascorbyl Tetraisopalmitate, Lavandula Spica (Lavender) Flower Oil, Eucalyptus Globulus Leaf Oil, Lavandula Hybrida Oil, Sodium DNA, Tocopherol, Caprylic/Capric Triglyceride, Carbomer, Pentylene Glycol, Hydroxyphenyl Propamidobenzoic Acid, Bisabolol, Zingiber Officinale (Ginger) Fruit Extract, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Dipotassium Glycyrrhizate, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Dimethicone/ PEG-10/15 Crosspolymer, PEG/ PPG-18/18 Dimethicone, Glycerin, Cyclomethicone, Tocopheryl Acetate, Disodium EDTA, Sodium Benzoate, Sodium Chloride, Sodium Citrate, Ethylhexylglycerin, Phenoxyethanol.

Questions or comments

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

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

super sensitive shield

spf

30

broad spectrum

NPN# 80031042

UltraCalming™

1.7 US FL OZ 50 mL **e**

dermalogica®

super sensitive shield

super sensitive shield



broad spectrum care system researched and developed by The International Dermal Institute

Drug Facts (continued)

Other information

■ Protect this product from excessive heat and direct sun.

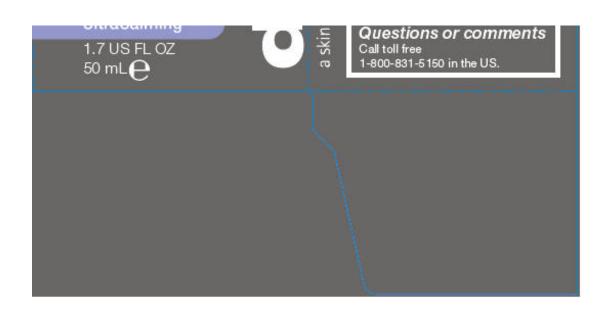
Inactive ingredients

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Water/Aqua/Eau, Cyclopentasiloxane,
Dicaprylyl Ether, Butylene Glycol,
Polyglyceryl-3 Polydimethylsiloxyethyl
Dimethicone, Lauryl PEG-9
Polydimethylsiloxyethyl Dimethicone,
Stearic Acid, Aluminum Hydroxide,
Dimethicone, Leuconostoc/Padish
Root Ferment Filtrate, Camellia
Sinensis Leaf Extract, Avena Sativa
(Oat) Kemel Extract, Boerhavia Diffusa
Root Extract, Oxothiazolidine, Citrullus
Vulgaris (Watermelon) Fruit Extract,
Pyrus Malus (Apple) Fruit Extract,
Pyrus Malus (Apple) Fruit Extract,
Sodium Hyaluronate, Sodium PCA,
Sodium Lactate, Lens Esculenta
(Lentil) Fruit Extract, Ascorbyl
Tetraisopalmitate, Lavandula Spica
(Lavender) Flower Oil, Eucalyptus
Globulus Leaf Oil, Lavandula Hybrida
Oil, Sodium DNA, Tocopherol,
Caprylic/Capric Triglyceride,
Carbomer, Pentylene Glycol,
Hydroxyphenyl Propamidobenzoic
Acid, Bisabolol, Zingiber
Officinale (Ginger) Fruit Extract,
Dimethicone/Inyl Dimethicone
Crosspolymer, Silica, Dipotassium
Glycyrhizate, Triethoxysilylethyl
Polydimethylsiloxyethyl Hexyl
Dimethicone, Dimethicone/
PEG-10/15 Crosspolymer, PEG/
PPG-18/18 Dimethicone, Glycerin,
Cyclomethicone, Tocopheryl Acetate,
Disodium EDTA, Sodium Benzoate,
Sodium Chloride, Sodium Citrate,
Ethylhexylglycerin, Phenoxyethanol.

NPN# 80031042

UltraCalming™



super sensitive shield



broad spectrum

Physical, Broad Spectrum sunscreen ideal for sensitized, reactive and recently resurfaced skin.

Natural mineral sunscreens help create a physical shield against photo damage and UV exposure. Contains ourexclusive UltraCalming™ Complex with Oat and bottanical actives to help minimize discomfort burning and minimize discomfort, burning and itching. Sheer formula provides optimal hydration and helps protect and reinforce barrier lipids, which are often compromised in sensitized skin conditions.

Formulated without artificial fragrances, colors or parabens. Product guaranteed when

Drug Facts

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Purpose Sunscreen

- Helps prevent sunburn.
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Warnings For external use only

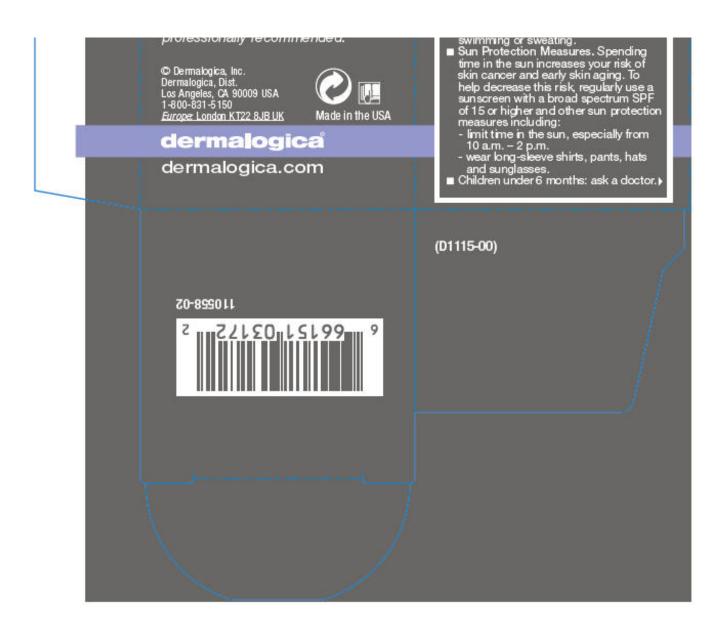
Do not use on damaged or broken skin

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

Stop use and ask a Doctor if rash

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- Directions
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 Reapply at least every two hours
 Use a water resistant sunscreen if



SUPER SENSITIVE SHIELD SPF 30

titanium dioxide and zinc oxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-150	
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	70 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	90 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Cyclomethicone 5 (UNII: 0THT5PCI0R)
Dicaprylyl Ether (UNII: 77JZM5516Z)
Butylene Glycol (UNII: 3XUS85K0RA)
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: 25G622K2RA)
Stearic Acid (UNII: 4ELV7Z65AP)
Aluminum Hydroxide (UNII: 5QB0T2IUN0)
Dimethicone (UNII: 92RU3N3Y1O)
Leuconostoc/Radish Root Ferment Filtrate (UNII: D2QHA03458)
Green Tea Leaf (UNII: W2ZU1RY8B0)
Oat (UNII: Z6J799EAJK)
Boerhavia Diffusa Root (UNII: KR0SR09KYL)
Oxothiazolidine (UNII: M6U1ZG59XD)
Watermelon (UNII: 231473QB6R)
Apple (UNII: B423VGH5S9)
Hyaluronate Sodium (UNII: YSE9 PPT4TH)
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)
Sodium Lactate (UNII: TU7HW0W0QT)
Lens Culinaris Fruit (UNII: ZYZ076G9JH)
Ascorbyl Tetraisopalmitate (UNII: 47143LT58A)
Lavender Oil (UNII: ZBP1YXW0H8)
Eucalyptus Oil (UNII: 2R04ONI662)
Lavandin Oil (UNII: 9RES347CKG)
Tocopherol (UNII: R0ZB2556P8)
Medium-Chain Triglycerides (UNII: C9H2L21V7U)
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)
Pentylene Glycol (UNII: 50C1307PZG)
Hydroxyphenyl Propamidobenzoic Acid (UNII: 25KRT26H77)
Levomenol (UNII: 24WE03BX2T)
Ginger (UNII: C5529 G5JPQ)
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)
Silicon Dioxide (UNII: ETJ7Z6XBU4)
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)
PEG/PPG-18/18 Dimethicone (UNII: 9H0 AO7T794)
Glycerin (UNII: PDC6A3C0OX)
Cyclomethicone (UNII: NMQ347994Z)
.AlphaTocopherol Acetate (UNII: 9E8X80D2L0)
Edetate Disodium (UNII: 7FLD91C86K)
Sodium Benzoate (UNII: OJ245FE5EU)
Sodium Chloride (UNII: 451W47IQ8X)
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)
Ethylhexylglycerin (UNII: 147D247K3P)
Phenoxyethanol (UNII: HIE492ZZ3T)
Product Characteristics

Froduct Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-150-02	1 in 1 CARTON	03/05/2012	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68479-150-01	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2012	
3	NDC:68479-150-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2012	
4	NDC:68479-150-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	03/05/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/05/2012	

Labeler - Dermalogica, Inc. (177698560)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosway		620899877	MANUFACTURE(68479-150)	

Establishment			
Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 110 4729	MANUFACTURE(68479-150)

Revised: 12/2017 Dermalogica, Inc.