

TOTAL EYE CARE SPF 15- 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.

Total Eye Care

Drug Facts

Active ingredient

Titanium Dioxide (5.0%)

Purpose

Sunscreen

Use

- 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 evenly 15 minutes before sun exposure.
- Reapply at least every 2 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 take 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, C12-15 Alkyl Ethylhexanoate, Glycerin, Butylene Glycol, Silica, Thermus Thermophilus Ferment, Lactic Acid, Potassium Cetyl Phosphate, Cetearyl Alcohol, Betaine, Glyceryl Stearate SE, Magnesium Aluminum Silicate, PEG-100 Stearate, Saccharomyces Cerevisiae Extract, Rhodiola Rosea Root Extract, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Bisabolol, Allantoin, Sodium PCA, Tocopheryl Acetate, Xanthan Gum, Dimethicone, Triethoxycaprylylsilane, Tocopherol, Cetearth-20, Sodium Hydroxide, Silica Dimethyl Silylate, Tetrasodium Glutamate Diacetate, Salicylic Acid, Potassium Sorbate, Ethylhexylglycerin, Benzyl Alcohol, Linalool, Limonene, Mica, Phenoxyethanol, Iron Oxides (CI 77492, CI 77491).

Questions or comments?

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

PRINCIPAL DISPLAY PANEL - 15 mL Tube Carton

total
eye
care

spf
15
broad
spectrum

dermalogica®

0.5 US FL OZ
15 mL e

total
eye
care

total
eye
care

spf
15 broad
spectrum

0.5 US FL OZ
15 mL e

dermalogica[®]

professional-grade skin care by The International Dermal Institute

Dermalogica invests in the potential of women entrepreneurs worldwide. Join us at joinFITE.org.



Made in the USA

© Dermalogica, LLC
Dermalogica, Dist.
Los Angeles, CA
90009 USA
1-800-831-5150
Europe: London
KT22 8JB UK

(D1608-00)

total
eye
care

spf
15 broad
spectrum

SPF eye cream helps conceal dark circles. A technologically-advanced eye treatment cream that smooths and retexturizes with gentle alpha hydroxy acids and plant extracts, helping to reduce the appearance of puffiness and fine lines. Optical light diffusers help conceal dark circles and a physical sunscreen helps to shield against further damage.

Formulated without artificial fragrances or colors. Product guaranteed when professionally recommended.

dermalogica
dermalogica.com

70-19911





Drug Facts

Active ingredient
Titanium Dioxide (5.0%)

Purpose
Sunscreen

Use

- 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 evenly 15 minutes before sun exposure.
■ Reapply at least every 2 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 take other sun protection measures including



Drug Facts (continued)

- 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, C12-15 Alkyl Ethylhexanoate, Glycerin, Butylene Glycol, Silica, Thermus Thermophilus Ferment, Lactic Acid, Potassium Cetyl Phosphate, Cetearyl Alcohol, Betaine, Glyceryl Stearate SE, Magnesium Aluminum Silicate, PEG-100 Stearate, Saccharomyces Cerevisiae Extract, Rhodiola Rosea Root Extract, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Bisabolol, Allantoin, Sodium PCA, Tocopheryl Acetate, Xanthan Gum, Dimethicone, Triethoxycaprylsilane, Tocopherol, Ceteareth-20, Sodium Hydroxide, Silica Dimethyl Silylate, Tetrasodium Glutamate Diacetate, Salicylic Acid, Potassium Sorbate, Ethylhexylglycerin, Benzyl Alcohol, Linalool, Limonene, Mica, Phenoxethanol, Iron Oxides (CI 77492, CI 77491).

Questions or comments?
Call toll free
1-800-831-5150
in the US

(D1608-00)

dermalogica

TOTAL
EYE
CARE
SPF15

110661-01

Peel
Here

TOTAL EYE CARE SPF 15

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-608
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
C12-15 Alkyl Ethylhexanoate (UNII: GQJ580CH83)	
Glycerin (UNII: PDC6A3C0OX)	
Butylene Glycol (UNII: 3XUS85K0RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Betaine (UNII: 3SCV180C9W)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
PEG-100 Stearate (UNII: YD01N1999R)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
SEDUM ROSEUM ROOT (UNII: 3S5ITS5ULN)	
LEVOMENOL (UNII: 24WE03BX2T)	
Allantoin (UNII: 344S277G0Z)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Xanthan Gum (UNII: TTV12P4NEE)	
Dimethicone (UNII: 92RU3N3Y1O)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Tocopherol (UNII: R0ZB2556P8)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Silica Dimethyl Silylate (UNII: EU2PSP0G0W)	
Tetrasodium Glutamate Diacetate (UNII: 5EHL50I4MY)	
Salicylic Acid (UNII: O414PZ4LPZ)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Ethylhexylglycerin (UNII: 147D247K3P)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
Mica (UNII: V8A1AW0880)	

Phenoxyethanol (UNII: HIE492ZZ3T)

FERROUS OXIDE (UNII: G7036X8B5H)

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-608-02	1 in 1 CARTON	03/01/2018	
1		15 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-608-01	4 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2018	
3	NDC:68479-608-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	03/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2018	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant		083913913	MANUFACTURE(68479-608)

Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-608)

Revised: 12/2017

Dermalogica, Inc.