# DAILY DEFENSE SPF 15- avobenzone, octinoxate, octisalate, and oxybenzone 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.

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#### Daily Defense SPF 15

**Drug Facts** 

#### **Active Ingredients**

Avobenzone (3.0%), Octinoxate (6.5%), Octisalate (3.0%), Oxybenzone (3.5%).

#### 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
- Do not use on infants under 6 months old.

#### **Inactive ingredients**

Water/Aqua/Eau, Butylene Glycol, Caprylic/Capric Triglyceride, Glyceryl Stearate, Cetearyl Phosphate, Glycerin, Stearic Acid, Polyglyceryl-2 Stearate, Dimethicone, Lactamide MEA, Pyrus Malus (Apple) Fruit Extract, Dimethyl Capramide, Mahonia Aquifolium Root Extract, Lavandula Angustifolia (Lavender) Extract, Hydrolyzed Opuntia Ficus Indica Flower Extract, Triticum Vulgare (Wheat) Germ Extract, Saccharomyces Cerevisiae Extract, Lavandula Spica (Lavender) Flower Oil, Lavandula Hybrida Oil, Eucalyptus Globulus Leaf Oil, Sodium Hyaluronate, Dipotassium Glycyrrhizate, Palmitoyl Tripeptide-5, Sodium DNA, Tocopherol, Allantoin, Panthenol, Glycerin Crosspolymer, Ascorbyl Tetraisopalmitate, Carbomer, Polyquaternium-10, Cetyl Alcohol, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Disodium EDTA, Citric Acid, Potassium Sorbate, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol.

#### 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 - 100 mL Tube Carton

daily defense

spf 15 broad spectrum

dermalogica<sup>®</sup>

3.4 US FL OZ 100 mL e daily defense

daily defense

spf 15

broad spectrum Table Of International Dermal Institute

### Drug Facts (continued)

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skin care system resea

Ethylhexylglycerin, Hexylene Glycol.

#### Other information

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1-800-831-5150 in the US

## daily defense

3.4 US FL OZ

100 mL (



broad spectrum

Multi-tasking daytime lotion helps soothe post-shave irritation and shields against skin-aging UV rays. Non-greasy, non-chalky lotion is the perfect finish to your Shave routine. Effectively conditions and enhances skin's protective barrier, which is critical oost-shave. Helps fight ingrown hairs

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### Warnings

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Do not use on damaged or broken skin

and breakouts.

Antioxidant Wheat Germ and Vitamin E help defend against skin aging free radicals. Formulated without artificial fragrances and colors.

- lightweight formula absorbs fast for a shine free finish.
- provides UV protection with no greasy or chalky after-feel.
- · helps restore skin's natural moisture balance.

Ask your skin therapist for your free Shave Mapping<sup>sm</sup> skin analysis and customized Dermalogica prescription.

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

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



(D1118-00)

10-073011



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-800	

TOPICAL

Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	65 mg in 1 mL	
Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	30 mg in 1 mL	
Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y)	Oxybenzone	35 mg in 1 mL	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Glyceryl Monostearate (UNII: 230 O U9 XXE4)	
Cetyl Phosphate (UNII: VT07D6X67O)	
Glycerin (UNII: PDC6A3C0OX)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Dimethicone (UNII: 92RU3N3Y1O)	
N-Lactoyl Ethanolamine (UNII: 900T44YNC7)	
Apple (UNII: B423VGH5S9)	
Dimethyl Capramide (UNII: O29Y6X2JEZ)	
Mahonia Aquifolium Root (UNII: 746TB9VNDP)	
Lavandula Angustifolia Flowering Top (UNII: 9YT4B71U8P)	
Vitis Vinifera Seed (UNII: C34U15ICXA)	
Wheat Germ (UNII: YR3G369F5A)	
Saccharomyces Cerevisiae (UNII: 978D8U419H)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Panthenol (UNII: WV9CM0O67Z)	
Lavender Oil (UNII: ZBP1YXW0H8)	
Lavandin Oil (UNII: 9RES347CKG)	
Eucalyptus Oil (UNII: 2R04ONI662)	
Ascorbyl Tetraisopalmitate (UNII: 47143LT58A)	
Tocopherol (UNII: R0ZB2556P8)	
Allantoin (UNII: 344S277G0Z)	
Palmitoyl Tripeptide-5 (UNII: 2A3916MQHO)	
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
Sodium NA-22 (UNII: N2511Z637B)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	

Egg Phospholipids (UNII: 1Z74184RGV)	
Aminomethylpropanol (UNII: LU49E6626Q)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Xanthan Gum (UNII: TTV12P4NEE)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Caprylyl Glycol (UNII: 00 YIU5438 U)	
Hexylene Glycol (UNII: KEH0 A3F75J)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:68479-800-02	1 in 1 CARTON			
1		100 mL in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:68479-800-00	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	04/13/2012	

# Labeler - Dermalogica, Inc. (177698560)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosway		620899877	MANUFACTURE(68479-800)	

Establishment			
Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 110 4729	MANUFACTURE(68479-800)

Revised: 11/2015 Dermalogica, Inc.