

**SOLAR DEFENSE BOOSTER SPF50- avobenzone and octinoxate lotion**  
**Dermologica, 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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**Solar Defense Booster**  
**SPF50**

***Drug Facts***

**Active Ingredients**

Avobenzone 3.0%, Octinoxate 7.5%

**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
- Children under 6 months: ask a doctor

## **Inactive ingredients**

Water/Aqua, Butylene Glycol, Carthamus Tinctorius (Safflower) Oleosomes, C12-15 Alkyl Benzoate, Polysorbate 80, Ammonium Acryloyldimethyltaurate/VP Copolymer, Dimethyl Capramide, Nylon-12, Centella Asiatica Extract, Echinacea Purpurea Extract, Magnesium Ascorbyl Phosphate, Melissa Officinalis Leaf Extract, Camellia Oleifera Leaf Extract, Citrus Medica Limonum (Lemon) Peel Extract, Vitis Vinifera (Grape) Seed Extract, Lavandula Angustifolia (Lavender) Oil, Lecithin, Tocopherol, Allantoin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Ascorbyl Tetraisopalmitate, Cocamidopropyl PG-Dimonium Chloride Phosphate, Sorbitan Sesquicaprylate, Caprylic/Capric Triglyceride, Squalane, Carbomer, Sodium DNA, Polysorbate 60, Disodium EDTA, Sodium Benzoate, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol, Titanium Dioxide (CI 77891).

## **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 Bottle Carton**

solar  
defense  
booster

spf  
50

broad  
spectrum

DIN# 02382687

1.7 US Fl . Oz.

50 mL e

**dermalogica®**

solar  
defense  
booster

solar  
defense  
booster

spf  
50

broad  
spectrum

**dermalogica**<sup>®</sup>

skin care system researched and developed by The International Dermal Institute

### **Drug Facts** (continued)

#### ***Inactive ingredients***

Water/Aqua, Butylene Glycol, Carthamus Tinctorius (Safflower) Oleosomes, C12-15 Alkyl Benzoate, Polysorbate 80, Ammonium Acryloyldimethyltaurate/VP Copolymer, Dimethyl Capramide, Nylon-12, Centella Asiatica Extract, Echinacea Purpurea Extract, Magnesium Ascorbyl Phosphate, Melissa Officinalis Leaf Extract, Camellia Oleifera Leaf Extract, Citrus Medica Limonum (Lemon) Peel Extract, Vitis Vinifera (Grape) Seed Extract, Lavandula Angustifolia (Lavender) Oil, Lecithin, Tocopherol, Allantoin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Ascorbyl Tetraisopalmitate, Cocamidopropyl PG-Dimonium Chloride Phosphate, Sorbitan Sesquicaprylate, Caprylic/Capric Triglyceride, Squalane, Carbomer, Sodium DNA, Polysorbate 60, Disodium EDTA, Sodium Benzoate, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol, Titanium Dioxide (CI 77891).

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- Protect this product from excessive heat and direct sun

#### ***Questions or comments***

DIN# 02382687

1.7 US Fl. Oz.

50 mL 

a skin

**Comments**

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## solar defense booster



Add critical UV defense to your moisturizer or foundation with this Broad Spectrum sunscreen for all skin conditions.

Sophisticated, non-chalky formula forms an invisible shield against skin damaging environmental assault with Green Tea and Grape Seed extracts. Antioxidant vitamins C and E help improve skin smoothness and softness while providing added defense against skin-aging free radicals. Apply directly to face and neck for full SPF50 coverage, or mix equal parts with your moisturizer or foundation to add critical defense against skin-aging UV light. Formulated without artificial fragrances and colors.

*Product guaranteed when professionally recommended. Ask your skin therapist for a Face Mapping® skin analysis and your customized zone-by-zone prescription.*

## Drug Facts

### Active Ingredients

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 Dermalogica (Canada) Ltd.  
 Canada: Toronto, ON M5V 2T3



Made In  
the USA

**dermalogica**  
dermalogica.com

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(D1110-00)

Z0-801011



## SOLAR DEFENSE BOOSTER SPF50

avobenzone and octinoxate lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68479-000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	70 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)
NYLON-12 (UNII: 446U8J075B)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
ECHINACEA PURPUREA (UNII: QI7G114Y98)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)
LEMON PEEL (UNII: 72O054U628)
VITIS VINIFERA SEED (UNII: C34U15ICXA)
LAVENDER OIL (UNII: ZBP1YXW0H8)
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)
TOCOPHEROL (UNII: R0ZB2556P8)
ALLANTOIN (UNII: 344S277G0Z)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SQUALANE (UNII: GW89575KF9)
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)
HERRING SPERM DNA (UNII: 51FI676N6F)
POLYSORBATE 60 (UNII: CAL22UVI4M)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-000-02	1 in 1 CARTON		
1		50 mL in 1 BOTTLE, PLASTIC		
2	NDC:68479-000-00	2 mL in 1 POUCH		
3	NDC:68479-000-04	125 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/13/2012	

**Labeler** - Dermalogica, Inc. (177698560)

### Establishment

Name	Address	ID/FEI	Business Operations
Gordon		008328619	MANUFACTURE(68479-000)

### Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-000)

Revised: 12/2013

Dermalogica, Inc.