

**DARK SPOT SUN DEFENSE BROAD SPECTRUM SPF 50- titanium dioxide and zinc oxide cream**

**Dr. Dennis Gross Skincare™, LLC**

*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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**Dark Spot Sun Defense  
Broad Spectrum SPF 50**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Titanium Dioxide 4.9%	Sunscreen
Zinc Oxide 4.42%	Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see ***Directions***), decreases 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
- Children under 6 months: ask a doctor
- 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 decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses

**Other information**

- Protect the product in this container from excessive heat and direct sun

**Inactive ingredients**

Acrylates/Carbamate Copolymer, Aluminum Hydroxide, Ascorbyl Glucoside, Benzyl Alcohol, BHT, Bis-ethylhexyl Hydroxydimethoxy Benzylmalonate, Boerhavia Diffusa Root Extract, Butylene Glycol,

C12-15 Alkyl Benzoate, Caprylyl Glycol, Carbomer, Carthamus Tinctorius (Safflower) Seed Oil, Citric Acid, Citrus Aurantium Dulcis (Orange) Oil, Citrus Aurantium Dulcis (Orange) Peel Extract, Coco-Caprylate/- Caprate, Coconut Alkanes, Disodium EDTA, Echium Plantagineum Seed Oil, Glycerin, Glycolic Acid, Hydrogenated Lecithin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Hydroxypropyl Cyclodextrin, Isohexadecane, Isononyl Isononanoate, Isopropyl Titanium Triisostearate, Magnesium Ascorbyl Phosphate, Melatonin, Nordihydroguaiaretic Acid Oenothera Biennis (Evening Primrose) Oil, Olea Europaea (Olive) Fruit Oil, Oleanolic Acid, Oryza Sativa (Rice) Extract, Palmitoyl Tripeptide-38, PEG-60 Almond Glycerides, Pentylene Glycol, Phenoxyethanol, Phospholipids, Polyhydroxystearic Acid, Polysorbate 60, Potassium Sorbate, Propanediol, Saccharide Isomerate, Sodium Benzoate, Sodium Citrate, Sodium Hyaluronate, Sodium PCA, Sphingolipids, Stearic Acid, Tetrahexyldecyl Ascorbate, Tocopherol, Water/Aqua/ Eau, Xanthan Gum, Zinc PCA

### **Questions?**

Call 1-888-830-7546 Monday through Friday, 9:00 AM to 5:00 PM EST

### **PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton**

FOR FACE & EYES

**Dr Dennis Gross**

**NO  
CHEMICAL  
FILTERS**

SKINCARE

**dark spot  
sun defense**

Broad Spectrum  
SPF 50 Sunscreen

1.7 fl oz/50ml e

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### What It Is:

This formula helps to prevent damage from UVA/UVB rays while reducing the appearance of dark spots, fine lines & wrinkles. It is free of chemical filters and absorbs quickly. Our unique Melatonin Defense Complex, with vitamins C & E and antioxidant melatonin protects against pollution and free radicals.

### Why You Need It:

Melatonin Defense Complex goes beyond traditional sunscreens by helping to diminish signs of hyperpigmentation and aging in addition to actively shielding skin from damaging environmental irritants.

### How To Use It:

Use daily in the AM. Start with clean, dry skin. Apply liberally over face, neck, and décolleté 15 minutes before sun exposure. Massage until visible formula melts into skin and completely disappears. Reapply every two hours. For children under 6 months of age, consult a doctor.

### Doctor's Tip:

Wear sunscreen daily. Even if you're just running to your car, that can add up to 20 minutes of sun exposure a day. That's over 120 hours a year.

FOR FACE & EYES



## Drug Facts (continued)

Oenothera Biennis (Evening Primrose) Oil, Olea Europaea (Olive) Fruit Oil, Oleoalif Acid, Oryza Sativa (Rice) Extract, Palmitoyl Tripeptide-38, PEG-60 Almond Glycides, Pentylene Glycol, Phenoxyethanol, Phospholipids, Polyhydroxysebacic Acid, Polysorbate 60, Potassium Sorbate, Propanediol, Saccharide Isomerate, Sodium Benzoate, Sodium Citrate, Sodium Hyaluronate, Sodium PCA, Sphingolipids, Stearic Acid, Tetrahexyldecyl Ascorbate, Tocopherol, Water/Aqua/Eau, Xanthan Gum, Zinc PCA

### Questions?

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Dist. NY NY 10022  
EU Responsible Person  
Borner, Rueda In Coyens 10 A,  
DE-3170 WALSACE  
Made in USA/Produced in: East-USA  
dgskincare.com



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UPC/FPO  
prints black on white bkgd

BA531510

BH531510.044

# DARK SPOT SUN DEFENSE BROAD SPECTRUM SPF 50

titanium dioxide and zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58633-315
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	49 mg in 1 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	44.2 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>Isononyl Isononanoate</b> (UNII: S4V5BS6GCX)	
<b>Safflower Oil</b> (UNII: 65UEH262IS)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Coconut Alkanes</b> (UNII: 1E5KJY107T)	
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)	
<b>Melatonin</b> (UNII: JL5DK93RCL)	
<b>Ascorbyl Glucoside</b> (UNII: 2V52R0NHXW)	
<b>Magnesium Ascorbyl Phosphate</b> (UNII: 0R822556M5)	
<b>Tetrahexyldecyl Ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>Boerhavia Diffusa Root</b> (UNII: KR0SR09KYL)	
<b>Echium Plantagineum Seed Oil</b> (UNII: PIB7XBU8XW)	
<b>Rice Germ</b> (UNII: 7N2B70SFEZ)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>Saccharide Isomerate</b> (UNII: W8K377W98I)	
<b>Orange Peel</b> (UNII: T19T76XD44)	
<b>Evening Primrose Oil</b> (UNII: 3Q9L08K71N)	
<b>Oleanolic Acid</b> (UNII: 6SMK8R7TGJ)	
<b>Palmitoyl Lysyldioxymethionyllysine</b> (UNII: T7A529FB8O)	
<b>Lecithin, Soybean</b> (UNII: 1DI56QDM62)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	
<b>SOY SPHINGOLIPIDS</b> (UNII: P491F5HP1U)	
<b>Glycolic Acid</b> (UNII: 0WT12SX38S)	
<b>Sodium Pyrrolidone Carboxylate</b> (UNII: 469OTG57A2)	
<b>Zinc Pidolate</b> (UNII: C32PQ86DH4)	
<b>Hydrogenated Soybean Lecithin</b> (UNII: H1109Z9J4N)	

<b>ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER</b> (UNII: R0R8I3X29J)
<b>Coco-Caprylate/Caprates</b> (UNII: 8D9H4QU99H)
<b>Isohexadecane</b> (UNII: 918X1OUF1E)
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)
<b>Masoprocol</b> (UNII: 7B08G1BYQU)
<b>Aluminum Hydroxide</b> (UNII: 5QB0T2IUN0)
<b>Bis-ethylhexyl Hydroxydimethoxy Benzylmalonate</b> (UNII: 7D4Q5YJ8NV)
<b>PEG-60 Almond Glycerides</b> (UNII: 4Y0E651N0F)
<b>Propanediol</b> (UNII: 5965N8W85T)
<b>Isopropyl Titanium Triisostearate</b> (UNII: 949E3KBJ1I)
<b>Butylated Hydroxytoluene</b> (UNII: 1P9D0Z171K)
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)
<b>Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked)</b> (UNII: 4Q93RCW27E)
<b>Polyhydroxystearic Acid (2300 MW)</b> (UNII: YXH47AOU0F)
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)
<b>Hydroxypropyl .Beta.-Cyclodextrin</b> (UNII: 1I96OHX6EK)
<b>Sodium Citrate</b> (UNII: 1Q73Q2JULR)
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)
<b>Orange Oil</b> (UNII: AKN3KSD11B)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58633-315-10	1 in 1 CARTON		
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58633-315-60	7 mL in 1 TUBE; 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	04/24/2015	

## Establishment

Name	Address	ID/FEI	Business Operations
PhytogenX		010297942	MANUFACTURE(58633-315) , PACK(58633-315)

Revised: 4/2015

Dr. Dennis Gross Skincare™, LLC