

**PRISMA PROTECT SPF 30- avobenzone, homosalate, octisalate, and octocrylene 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.*

-----

**Prisma Protect SPF 30**

***Drug Facts***

**Active Ingredients**

Avobenzone (3.0%)  
Homosalate (10.00%)  
Octisalate (5.00%)  
Octocrylene (10.00%)

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun care 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 30 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 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

- Do not use on infants under 6 months old

#### **Other information**

- Protect this product from excessive heat and direct sun.

#### **Inactive ingredients**

Water/Aqua/Eau, Silica, Butylene Glycol, Coconut Alkanes, Dimethicone, Glycerin, Dimethyl Capramide, Polyglyceryl-2 Stearate, VP/Eicosene Copolymer, Chlorella Vulgaris Extract, Palmitoyl Oligopeptide, Saccharide Isomerate, Zingiber Officinale (Ginger) Root Oil, Sclareolide, Tocopherol, Camellia Sinensis Leaf Extract, Tocopheryl Acetate, Coco-Caprylate/Caprates, Glyceryl Stearate SE, PEG-100 Stearate, Potassium Cetyl Phosphate, Arachidyl Alcohol, Dimethicone Crosspolymer, Behenyl Alcohol, Benzyl Alcohol, Caprylic/Capric Triglyceride, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arachidyl Glucoside, Ethylhexylglycerin, Methicone, Sodium Hydroxide, Trisodium Ethylenediamine Disuccinate, Citric Acid, Sodium Citrate, Caprylyl Glycol, Propanediol, Polyvinyl Alcohol, Sodium Benzoate, Potassium Sorbate, 1,2-Hexanediol, Phenoxyethanol.

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

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

#### **PRINCIPAL DISPLAY PANEL - 12 mL Tube Carton**

prisma  
protect

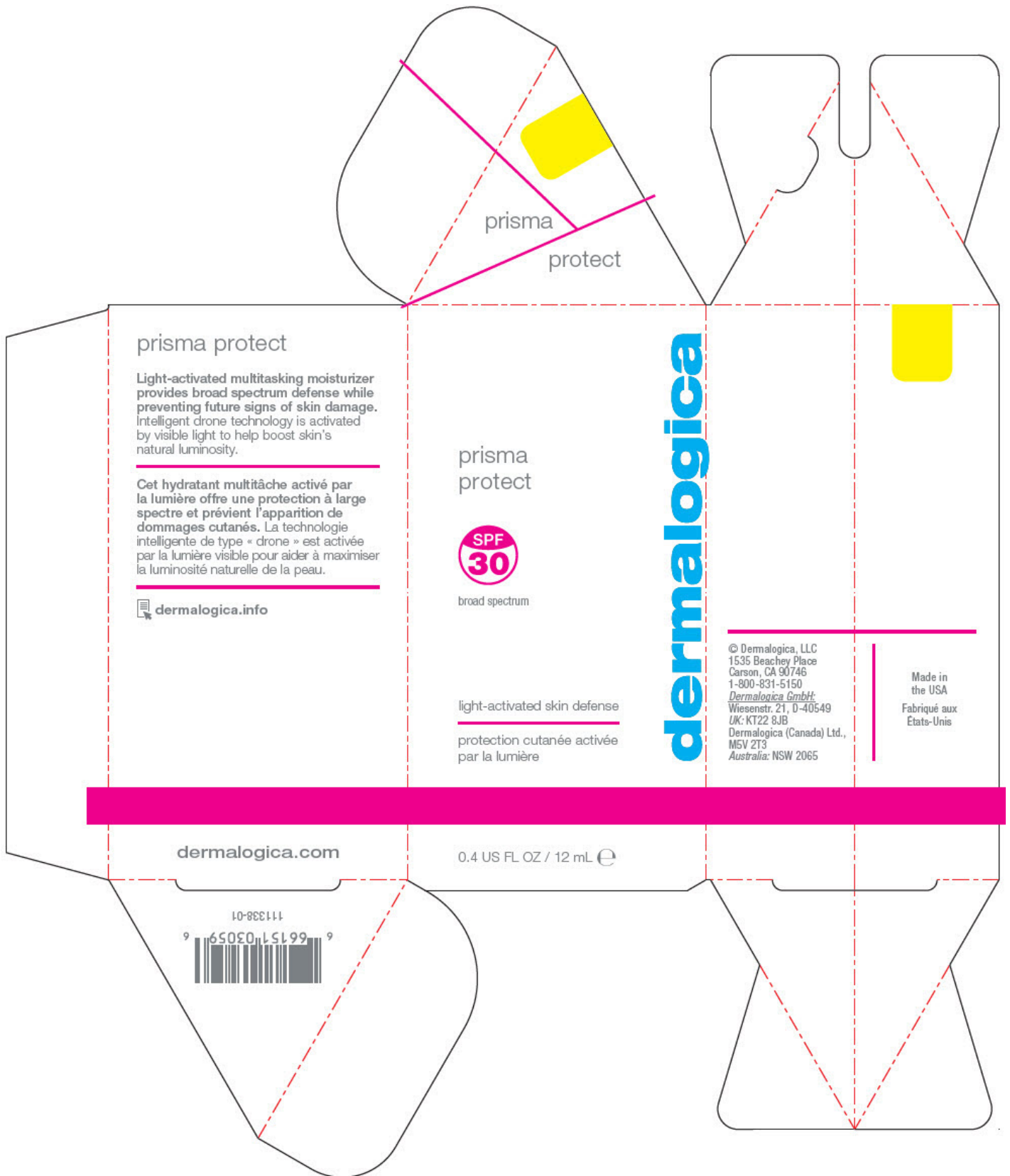
SPF  
30

broad spectrum

dermalogica

light-activated skin defense

0.4 US FL OZ / 12 mL e



PeeTHere ▶	
<b>prisma protect spf30</b>	
<b>Drug Facts</b>	
<b>Active Ingredients</b>	
Avobenzone (3.0%)	
Homosalate (10.00%)	

<b>Drug Facts</b> (continued)
<b>Stop use and ask a doctor</b>
■ if rash occurs.
<b>Keep out of reach of children</b>

Octisalate (5.00%)  
Octocrylene (10.00%)

**Purpose**  
Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun care 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. ▶

111330-00

- Other information.**
- If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally 30 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 ▶

**Drug Facts**

(continued)

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
- Do not use on infants under 6 months old ▶

**Drug Facts**

(continued)

**Other information**

- Protect this product from excessive heat and direct sun.

**Inactive ingredients**

Water/Aqua/  
Eau, Silica,  
Butylene Glycol,  
Coconut Alkanes,  
Dimethicone,  
Glycerin, Dimethyl  
Capramide,  
Polyglyceryl-2  
Stearate, VP/  
Eicosene  
Copolymer,  
Chlorella Vulgaris  
Extract, Palmitoyl  
Oligopeptide,  
Saccharide  
Isomerate,  
Zingiber Officinale  
(Ginger) Root  
Oil, Sclareolide, ▶

**Drug Facts**

(continued)

Tocopherol,  
Camellia Sinensis

**Drug Facts**

(continued)

Disuccinate,

Camellia Siniensis  
 Leaf Extract,  
 Tocopheryl  
 Acetate, Coco-  
 Caprylate/  
 Caprate, Glyceryl  
 Stearate SE,  
 PEG-100 Stearate,  
 Potassium Cetyl  
 Phosphate,  
 Arachidyl Alcohol,  
 Dimethicone  
 Crosspolymer,  
 Behenyl Alcohol,  
 Benzyl Alcohol,  
 Caprylic/Capric  
 Triglyceride,  
 Xanthan Gum,  
 Acrylates/C10-30  
 Alkyl Acrylate  
 Crosspolymer,  
 Arachidyl  
 Glucoside,  
 Ethylhexylglycerin,  
 Methicone,  
 Sodium Hydroxide,  
 Trisodium  
 Ethylenediamine ▶

Citric Acid,  
 Sodium Citrate,  
 Caprylyl Glycol,  
 Propanediol,  
 Polyvinyl Alcohol,  
 Sodium Benzoate,  
 Potassium Sorbate,  
 1,2-Hexanediol,  
 Phenoxyethanol.

**Questions or  
comments?**

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

## PRISMA PROTECT SPF 30

avobenzone, homosalate, octisalate, and octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68479-805
<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>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Coconut Alkanes</b> (UNII: 1E5KJY107T)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Dimethyl Capramide</b> (UNII: O29Y6X2JEZ)	

<b>Polyglyceryl-2 Stearate</b> (UNII: 253MC0P0YV)
<b>Vinylpyrrolidone/Eicosene Copolymer</b> (UNII: 035MV9S1C3)
<b>Chlorella Vulgaris</b> (UNII: RYQ4R60M02)
<b>Grapefruit Oil</b> (UNII: YR377U58W9)
<b>Saccharide Isomerate</b> (UNII: W8K377W98I)
<b>Ginger Oil</b> (UNII: SAS9Z1SVUK)
<b>Sclareolide</b> (UNII: 37W4O0O6E6)
<b>Tocopherol</b> (UNII: R0ZB2556P8)
<b>Green Tea Leaf</b> (UNII: W2ZU1RY8B0)
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)
<b>Coco-Caprylate/Caprates</b> (UNII: 8D9H4QU99H)
<b>Glyceryl Stearate SE</b> (UNII: FCZ5MH785I)
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)
<b>Potassium Cetyl Phosphate</b> (UNII: 03KCY6P7UT)
<b>Arachidyl Alcohol</b> (UNII: 1QR1QRA9BU)
<b>Dimethicone Crosspolymer (450000 MPA.S at 12% in Cyclopentasiloxane)</b> (UNII: UF7620L1W6)
<b>Docosanol</b> (UNII: 9G1OE216XY)
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)
<b>Medium-chain Triglycerides</b> (UNII: C9H2L21V7U)
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)
<b>Ethyl Acrylate/Methacrylic Acid/Stearth-20 Methacrylate Copolymer</b> (UNII: EPA1872R1N)
<b>Arachidyl Glucoside</b> (UNII: 6JVW35JOOJ)
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)
<b>Methicone (20 CST)</b> (UNII: 6777U11MKT)
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)
<b>Trisodium Ethylenediamine Disuccinate</b> (UNII: YA22H34H9Q)
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)
<b>Sodium Citrate, Unspecified Form</b> (UNII: 1Q73Q2JULR)
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)
<b>Propanediol</b> (UNII: 5965N8W85T)
<b>Polyvinyl Alcohol, Unspecified</b> (UNII: 532B59J990)
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)
<b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-805-04	1 in 1 CARTON	03/07/2019	
1		177 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-805-02	50 mL in 1 TUBE; Type 0: Not a Combination Product	03/07/2019	
3	NDC:68479-805-01	12 mL in 1 TUBE; Type 0: Not a Combination Product	03/07/2019	
4	NDC:68479-805-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	03/07/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/07/2019	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosway		620899877	MANUFACTURE(68479-805)

Revised: 3/2019

Dermalogica, Inc.