

PROTECTION 50 BODY- avobenzone and octinoxate 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.

Protection 50 Body

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 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 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, Butylene Glycol, C12-15 Alkyl Benzoate, Carthamus Tinctorius (Safflower) Oleosomes, Cyclopentasiloxane, Aluminum Starch Octenylsuccinate, Cetearyl Phosphate, Polyglyceryl-2 Stearate, Dimethyl Capramide, VP/Eicosene Copolymer, Artemisia Pallens Flower Oil, Cananga Odorata Flower Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Paradisi (Grapefruit) Peel Oil, Pelargonium Graveolens Flower Oil, Tagetes Minuta Flower Oil, Sodium Hyaluronate, Dipotassium Glycyrrhizate, Caprylic/Capric Glycerides, Arachidyl Alcohol, Behenyl Alcohol, Arachidyl Glucoside, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Disodium EDTA, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol.

Questions or comments

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

PRINCIPAL DISPLAY PANEL - 156 mL Tube Carton

protection
50

sport

spf
50

broad
spectrum

UVA high protection

5.3 US FL OZ
156 mL e

dermalogica[®]

protection
50
sport

protection
50
sport



[®]
malogica

ed and developed by The International Dermal Institute

Drug Facts (continued)

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Questions or comments

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

UVA high protection
5.3 US FL OZ
156 mL e

derm

a skin care system research

protection
50
sport



**Water-resistant (40 minutes),
Broad Spectrum sun protection
for face and body.**

This sheer solar protection treatment

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defends against prolonged skin damage from UV light and environmental assault. Oleosome microspheres help enhance SPF performance and counteract moisture loss triggered by extended daylight exposure. Lightweight formula helps neutralize damage and bind moisture to skin without a greasy after-feel.

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

dermalogica
dermalogica.com

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Europe: London KT22 7TW UK



(D1223-00)

110904-00



PROTECTION 50 BODY

avobenzone and octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-230
Route of Administration	TOPICAL		

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	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Carthamus Tinctorius Seed Oleosomes (UNII: 9S60Q72309)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
Dimethyl Capramide (UNII: O29Y6X2JEZ)	
Davana Oil (UNII: CL439Y041G)	
Cananga Oil (UNII: 8YOY78GNNX)	
Orange Oil (UNII: AKN3KSD11B)	
Grapefruit Oil (UNII: YR377U58W9)	
Pelargonium Graveolens Flower Oil (UNII: 3K0J1S7QGC)	
Tagetes Minuta Flower Oil (UNII: 1T0ZMU8M8B)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Docosanol (UNII: 9G1OE216XY)	
Arachidyl Glucoside (UNII: 6JVW35JOOJ)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Xanthan Gum (UNII: TTV12P4NEE)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-230-02	1 in 1 CARTON		
1		156 mL in 1 TUBE		

2	NDC:68479-230-01	22 mL in 1 TUBE		
3	NDC:68479-230-00	2 mL in 1 POUCH		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352		08/08/2013	

Labeler - Dermalogica, Inc. (177698560)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosway		620899877	MANUFACTURE(68479-230)

Establishment			
Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 110 4729	MANUFACTURE(68479-230)

Revised: 2/2014

Dermalogica, Inc.