

PROTECTION 50 SPORT- homosalate, octocrylene, octisalate, and avobenzone lotion
Dermalogica, 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.

Protection 50 Sport

Drug Facts

Active ingredients

Avobenzone (3.0%)
Octisalate (5.0%)
Homosalate (10.0%)
Octocrylene (10.0%)

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:
 - after 80 minutes of swimming or sweating.
 - immediately after towel drying.
 - at least every 2 hours.
- **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, Carthamus Tinctorius (Safflower) Oleosomes, Butylene Glycol, Dimethicone, Methyl Methacrylate Crosspolymer, C15-19 Alkane, VP/ Eicosene Copolymer, Silica, Dimethyl Capramide, Polyglyceryl-2 Stearate, Squalane, Dipotassium Glycyrrhizate, Arachidyl Glucoside, Glyceryl Stearate SE, PEG-100 Stearate, Arachidyl Alcohol, Potassium Cetyl Phosphate, Dimethicone Crosspolymer, Behenyl Alcohol, Xanthan Gum, Acrylates/C10- 30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Sodium Hydroxide, Citric Acid, 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

80 minutes

water-resistant

5.3 US FL OZ / 156 mL e

dermalogica



protection 50
sport
spf 50

protection
50
sport



broad spectrum
large spectre

ermalogica

Drug Facts (continued)

Other information

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Questions or comments

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1-800-831-5150 in the US

6 ¹/₄

80 minutes
water-resistant

résiste à l'eau
pendant 80 minutes

de

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D-40549 Düsseldorf • UK: KT22
8JB • Dermalogica (Canada) Ltd.,
M5J 2M4 • Australia: NSW 2065*



Made in the USA | Fabriqué aux États-Unis

5.3 US FL OZ / 156 mL e



MIX
Paper from
responsible sources
FSC®

protection 50 sport spf 50

Water-resistant (80 minutes), Broad Spectrum sun protection for face and body. This sheer solar protection treatment defends against skin damage from UV light and environmental assault. Oleosome microspheres help enhance 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.

Protection solaire à large spectre résistante à l'eau (80 minutes) pour le visage et le corps. Cet écran solaire léger protège la peau des dommages causés par les rayons UV et des

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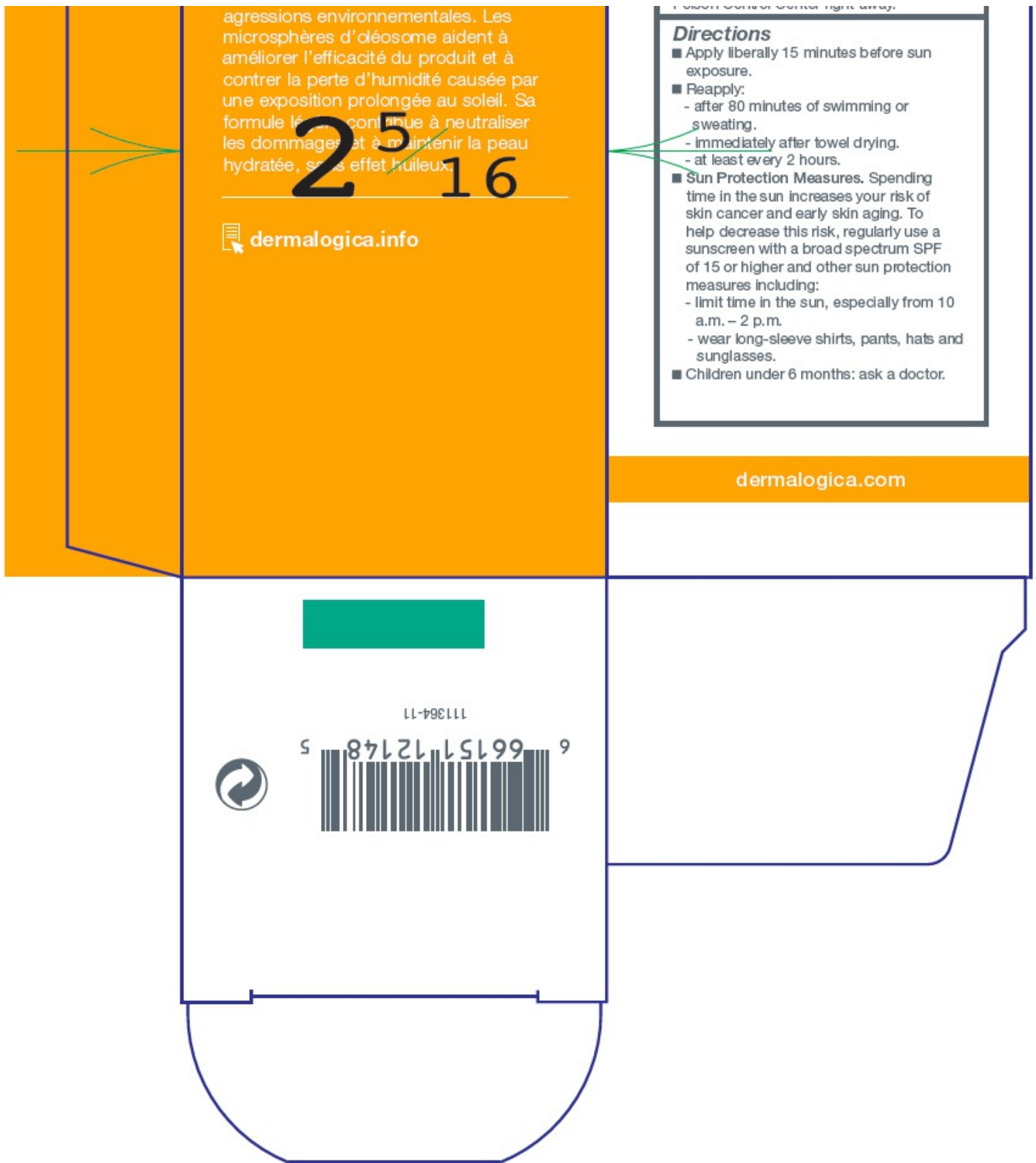
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-232
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	10 mg in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	10 mg in 100 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 mg in 100 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
Dimethicone (UNII: 92RU3N3Y1O)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
C15-19 Alkane (UNII: CI87N1IM01)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Dimethyl Capramide (UNII: O29Y6X2JEZ)	
Polyglyceryl-2 Stearate (UNII: 253MC0P0YV)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Squalane (UNII: GW89575KF9)	
DOCOSANOL (UNII: 9G1OE216XY)	
Xanthan Gum (UNII: TTV12P4NEE)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
Arachidyl Glucoside (UNII: 6JVV35JOOJ)	
Benzyl Alcohol (UNII: LKG8494WBH)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Tetrasodium Glutamate Diacetate (UNII: 5EHL50I4MY)	
Sodium Hydroxide (UNII: 55X04QC32I)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-232-02	1 in 1 CARTON	08/05/2019	
1		156 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-232-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	08/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/05/2019	

Labeler - Dermalogica, LLC. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
Cosway		052400223	MANUFACTURE(68479-232)

Revised: 7/2022

Dermalogica, LLC.