

DERMATONE SPF 30- avobenzone, homosalate, octisalate, octocrylene lotion
Dermatone Labs LLC

Dermatone SPF 30 Sunscreen Lotion

Active ingredients

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Octocrylene 10.0%

Uses

- Helps prevent sunburn, higher SPF gives more sunburn protection
- retains SPF after XX minutes of activity in the water or sweating
- provides moderate protection against 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.

Highly Flammable: Do not apply or use product near heat, flame, or while smoking.

When using this product:

- keep out of eyes. Rinse with water to remove.
- Keep away from face to avoid breathing it.
- Do not puncture or incinerate, Contents under pressure
- Do not store at temperature above 120°F

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

When using this product:

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- Keep away from face to avoid breathing it.
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Behenyl Alcohol

BHT

Butyloctyl Salicylate

Caprylyl Methicone

Dimethicone

Dimethyl Capramide

Disodium EDTA

Ethylhexyl Stearate

Ethylhexylglycerin

Glyceryl Stearate

Hydrated Silica

PEG-100 Stearate

Phenoxyethanol

Polyester-8

Sodium Polyacrylate

Styrene/ Acrylate Copolymer

Trideceth-6

Trimethylsiloxysilicate

VP/Hexadecene Copolymer

Water

Xanthan Gum

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.

- Reapply:

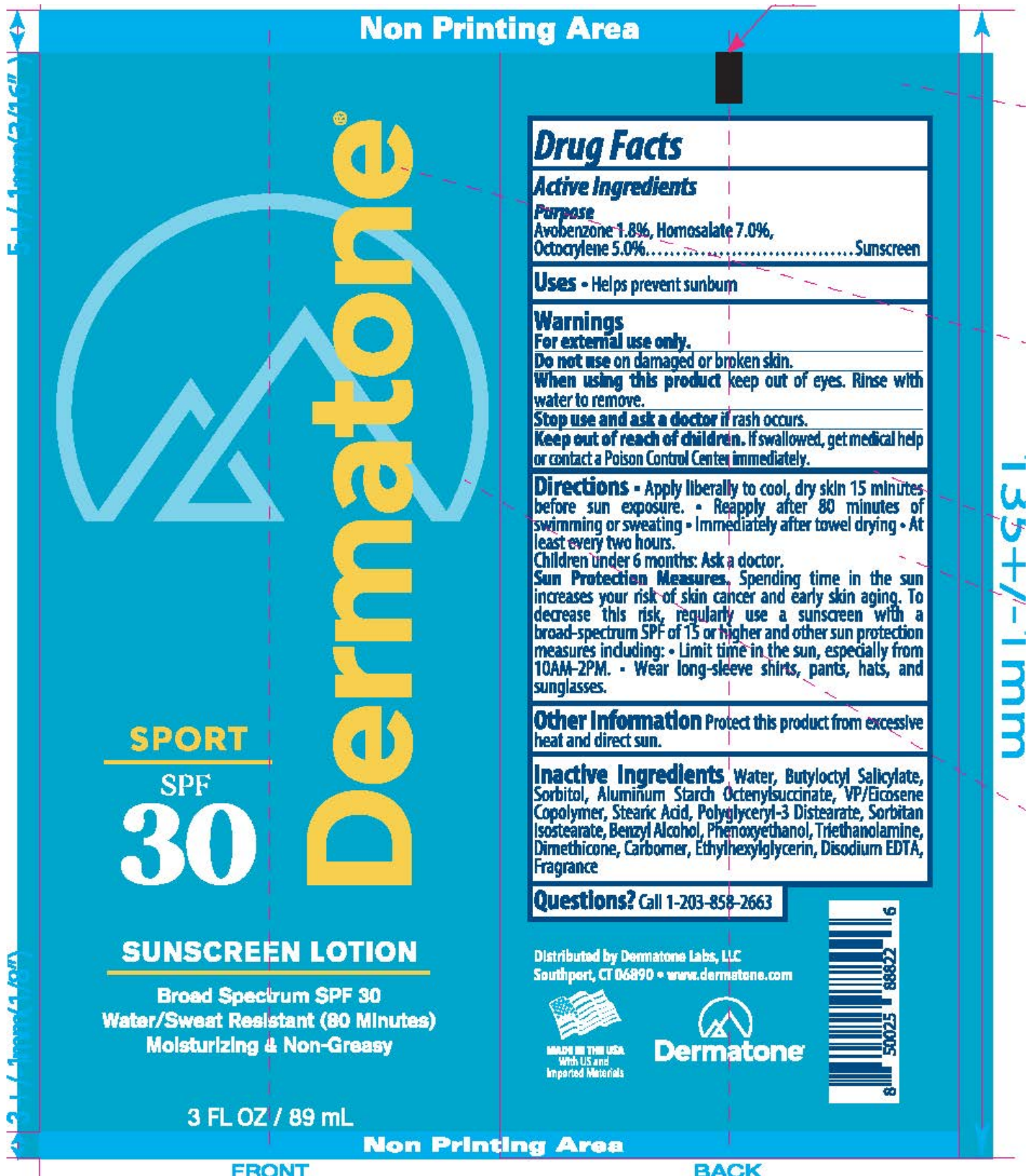
after 80 minutes of swimming or sweating

immediately after towel drying

at least every 2 hours

- Hold container 4 to 6 inches from the skin to apply.
- Do not spray directly into face. Spray on hands then apply to face.
- Do not apply in windy conditions.
- Use in a well-ventilated area.
- For sunscreen use
- apply to all areas of the skin exposed to the sun.
- Reapply as needed or after towel drying, swimming, or sweating.

Sunscreen



DERMATONE SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54414-048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54414-048-01	89 mL in 1 TUBE; Type 0: Not a Combination Product	06/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/26/2022	

Labeler - Dermatone Labs LLC (100928460)**Registrant** - Inspec Solutions LLC (081030372)

Establishment			
Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(54414-048)

Revised: 4/2025

Dermatone Labs LLC