

SPF RX - SPORT SUNSCREEN SPF 50- homosalate, octocrylene, octisalate, avobenzone cream
Cal Pharma 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.

ACTIVE INGREDIENTS

Homosalate 12%

Octocrylene 4.8%

Octisalate 4%

Avobenzone 2.4%

Purpose

Sunscreen

USES

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer, early skin aging 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 product is 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
- At least every 2 hours. Immediately after towel drying.

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer & early skin aging. To 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.

INACTIVE INGREDIENTS

Benzoic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glycereth-2 Cocoate, Stearyl/Octyldodecyl Citrate Crosspolymer, Phenoxyethanol, Propylene Glycol, Sodium Chloride, Water

OTHER INFORMATION

Protect this product from excessive heat and direct sun.

Drug Facts **SPF Rx**

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Distributed By:
 Cal Pharma
www.cal-pharma.com
 MADE IN THE USA

Your Prescription for
Sunscreen Naturally

Broad Spectrum Protection

Sport Sunscreen

Water Resistant (80 minutes)

SPF 50

4 fl oz / 120 ml

SPF RX - SPORT SUNSCREEN SPF 50

homosalate, octocrylene, octisalate, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55628-8834
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	12 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4.8 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55628-8834-4	120 g in 1 TUBE; Type 0: Not a Combination Product	07/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/30/2017	

Labeler - Cal Pharma LLC (078721283)**Registrant** - Cal Pharma LLC (078721283)**Establishment**

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(55628-8834)