# SPF RX - SPORT SUNSCREEN SPF 30- 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.

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#### 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.



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homosalate, octocrylene, octisalate, avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55628-8824
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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	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: 8 SKN0 B0 MIM)		
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 5) (UNII: 035JKJ76MT)		
EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)		
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)		
PHENO XYETHANOL (UNII: HIE49 2ZZ3T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
WATER (UNII: 059QF0KO0R)		

Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:55628-8824-4	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(55628-8824)	

Revised: 7/2017 Cal Pharma LLC