

**SPF RX - ANTI-AGING SUNSCREEN SPF 30- avobenzene, octisalate, octocrylene, oxybenzone 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**

Avobenzene 2.75%

Octisalate 4.75%

Octocrylene 2.80%

Oxybenzone 4.25%

**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**

Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aleurites Moluccana Seed Oil, Allantoin, Aloe Barbadensis Leaf Extract, Butyloctyl Salicylate, C12-13 Alcohols, C12-15 Alkyl Benzoate, Camellia Sinensis Leaf Extract, Cetearyl Alcohol, Cetyl Phosphate, Cyclopentasiloxane, Dimethicone, Ethylhexylglycerin, Glycerin, Helianthus Annuus Seed Oil, Hydroxyethyl Acrylate/Sodium

Acryloyldimethyl Taurate Copolymer, Macadamia Ternifolia Seed Oil, Magnesium Silicate, Methylisothiazolinone, Phenoxyethanol, Polysorbate 60, Squalane, Tetrasodium EDTA, Tocopherol, Tocopheryl Acetate, Water, Xanthan Gum

## OTHER INFORMATION

Protect this product from excessive heat and direct sun.

<b>Drug Facts</b>		
<b>ACTIVE INGREDIENTS</b>		
Avobenzone 2.75%	}	Purpose Sunscreen
Octisalate 4.75%		
Octocrylene 2.80%		
Oxybenzone 4.25%		
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When using this product keep out of eyes. Rinse with water to remove.		
Stop use and ask a doctor if rash occurs.		
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<b>DIRECTIONS</b>		
Apply liberally 15 minutes before sun exposure. Reapply:		
- After 80 minutes of swimming or sweating		
- At least every 2 hours. Immediately after towel drying.		
<b>Sun Protection Measures:</b> 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:		
<ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul>		
Children under 6 months. Ask a doctor.		
<b>INACTIVE INGREDIENTS:</b> Acrylates/C12-22, Alkyl Methacrylate, Aleurites Moluccana Seed Oil, Allantoin (Comfrey Fruit Derived), Aloe Barbadensis (Aloe Vera) Leaf, Butyloctyl Salicylate, (SPF Booster), C12-13 Alcohols, C12-15 Alkyl Benzoate, Camillia Sinensis (Green Tea) Leaf Extract, Cetearyl Alcohol (Plant Derived), Cetyl Phosphate, Cyclopentasiloxane, Dimethicone, Ethylhexylglycerin (Plant Derived) Glycerin (Plant Derived), Helianthus Annuus (Sunflower) Seed Oil, Hydroxyethyl Acrylate Sodium Acryloyldimethyltaurate, Copolymer, Macadamia Ternifolia Seed Oil, Magnesium Silicate, Methylisothiazolinone, Panthenolxyethanol, Polysorbate 60, Squalane, Tetrasodium EDTA, Tocopherol (Antioxidant), Tocopheryl Acetate (Vitamin E Acetate), Water (Aqua), Xanthan Gum		
<b>OTHER INFORMATION</b>		
Protect this product from excessive heat and direct sun.		
MADE IN THE USA 		
Distributed By:		
Cal Pharma 		
www.cal-pharma.com		
Toll Free 1-888-551-7778		

# SPF Rx

Your Prescription for  
Sunscreen Naturally

Broad Spectrum Protection  
**Anti-Aging Sunscreen**

# SPF 30

**WATER RESISTANT  
(80 MINUTES)**

120ml/4 fl oz

## SPF RX - ANTI-AGING SUNSCREEN SPF 30

avobenzone, octisalate, octocrylene, oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55628-8477
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.8 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.75 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.75 g in 100 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.25 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>(C10-C30)ALKYL METHACRYLATE ESTER</b> (UNII: XH2FQZ38D8)	
<b>ALEURITES MOLUCCANA SEED</b> (UNII: J87WJ3E7VW)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>C12-13 ALCOHOLS</b> (UNII: T7ZJT3I9X2)	
<b>DODECYL BENZOATE</b> (UNII: N4F51K239A)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL PHOSPHATE</b> (UNII: VT07D6X67O)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)	
<b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55628-8477-4	120 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/31/2017	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(55628-8477)

Revised: 7/2017

Cal Pharma LLC