

**SPF RX - SPF 50 SPEARMINT LIP BALM- octinoxate, zinc lipstick**  
**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**

Octinoxate 7.5%

Zinc 19%

**Purpose**

Sunscreen

**USES**

Helps prevent sunburn.

**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 at least every 2 hours. Children under 6 months, ask a doctor.

**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

**INACTIVE INGREDIENTS**

Helianthus Annuus (Sunflower) Seed Oil, Cera Alba (Beeswax), Olea Europaea (Olive) Fruit Oil, Flavor, Cannabis Sativa (Hemp) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, Aloe Barbadensis Leaf Extract.

**OTHER INFORMATION**

Protect this product from excessive heat and direct sun.

Distributed by: Cal Pharma

www.cal-pharma.com

## Drug Facts

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 7.5%.....	Sunscreen
Zinc 19%.....	Sunscreen
<b>Uses</b> : Helps prevent against sunburn	
<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> <li>• Children under 6 months. Ask a doctor.</li> </ul>	
<b>For external use only</b>	
Do not use on damaged or broken skin	
When using this product keep out of eyes. Rinse with water and 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.	
<b>Directions</b> <ul style="list-style-type: none"> <li>• Apply liberally 15 minutes before sun exposure</li> <li>• reapply at least every 2 hours</li> <li>• children under 6 months of age, ask doctor</li> </ul>	
<b>Inactive Ingredients</b> Sunflower Oil*, Beeswax, Extra Virgin Olive Oil*, Flavor, Hemp Seed Oil*, Rosemary Extract, Vitamin E, Aloe Vera. *Certified Organic	



### SPF RX - SPF 50 SPEARMINT LIP BALM

octinoxate, zinc lipstick

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55628-9585
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	19 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
WHITE WAX (UNII: 7G1J5DA97F)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55628-9585-0	4.2 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(55628-9585)

Revised: 7/2017

Cal Pharma LLC