

**SPF RX - SPF 15 SPEARMINT LIP BALM- octinoxate, octisalate, avobenzone,
octocrylene 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.

ACTIVE INGREDIENTS

Octinoxate 6.5%

Octisalate 5%

Avobenzone 2%

Octocrylene 1.5%

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 direct sun and excessive heat.

Distributed by: Cal Pharma Whittier, Ca www.cal-pharma.com

SPF 15 Spearmint Lip Balm

Drug Facts

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Octinoxate 6.5%	Sunscreen
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Octocrylene 1.5%	Sunscreen

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Warnings

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Stop use and ask a doctor if rash occurs. Keep out of reach of children. If swallowed get medical help or Contact Poison Control Center right away.

Directions:



- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- children under 6 months of age, ask doctor

Inactive Ingredients:
Sunflower Oil*, Beeswax, Extra Virgin Olive Oil*, Flavor, Hemp Seed Oil*, Rosemary Extract, Vitamin E, Aloe Vera.
*Certified Organic

Other Information
Protect this product from direct sun and excessive heat.




Your Prescription for
Sunscreen Naturally

SPF 15 Spearmint Lip Balm
Broad Spectrum Protection

Net Wt. 4.2 g/0.15 oz



SPF RX - SPF 15 SPEARMINT LIP BALM

octinoxate, octisalate, avobenzone, octocrylene lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55628-9575
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 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:55628-9575-0	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(55628-9575)

Revised: 7/2017

Cal Pharma LLC