

PEPPERMINT SPF 30 BROAD SPECTRUM LIP BALM- peppermint spf 30 broad spectrum lip balm stick

Raining Rose, Inc

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

Avobenzone 2.0%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

Purpose

Sunscreen

Warnings

For external use only

Do not use

on damaged or broken skin.

Stop Use and ask a doctor if

Rash Occurs

When Using this Product

Keep out of eyes. Rinse well with water to remove.

Keep out of reach of children

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure

Use a water resistant sunscreen if swimming or sweating

Reapply at least every 2 hours

Children under 6 months of age: **Ask a doctor**

Inactive ingredients:

Beeswax, coconut oil, castor oil, flavor, shea butter, cocoa butter.

Package Label

PEEL HERE FOR DRUG FACTS

Made in the USA

Broad Spectrum SPF 30 Sunscreen
Peppermint Lip Balm

Net Wt. .15 oz.

Drug Facts

Active Ingredients:		Purpose
Avobenzone	3.0%	Sunscreen
Homosalate	7.5%	
Octisalate	5.0%	
Octocrylene	2.5%	
Oxybenzone	6.0%	

Drug Facts (continued)

Uses • Helps prevent sunburn

Warnings

• For external use only • Do not use on damaged or broken skin • Stop use and ask a doctor if • rash occurs • When using this product • keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months of age: Ask a doctor
Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value 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 sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients: Beeswax, Coconut Oil, Castor Oil, Flavor, Shea Butter, Cocoa Butter.

Other Information

Protect this product from excessive heat and direct sun.

Dist. by: Company Name City State ZIP

L000000

SAFETY SEAL

PEPPERMINT SPF 30 BROAD SPECTRUM LIP BALM

peppermint spf 30 broad spectrum lip balm stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0555
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.13 g in 4.25 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.32 g in 4.25 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.25 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.11 g in 4.25 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.26 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEA BUTTER (UNII: K49155WL9Y)	
WHITE WAX (UNII: 7G1J5DA97F)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CASTOR OIL (UNII: D5340Y2I9G)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0555-1	4.25 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/17/2020	

Labeler - Raining Rose, Inc (083819404)