

VANILLA MINT LIP SPF 30 BALM- avobenzone, homosalate, octisalate, octocrylene, oxybenzone 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.

RR Vanilla Mint Lip Balm - 0201

PEEL HERE FOR DRUG FACTS
BROAD SPECTRUN SPF 30 Sunscreen
Vanilla Mint Lip Balm - 0201

Active Ingredients:

Avobenzone 3.0%
Homosalate 7.5%
Octisalate 5.0%
Octocrylene 2.5%
Oxybenzone 6.0%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

Warnings

For External Use Only

Do not use

on damaged or broken skin

Stop use and as 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.

If swallowed, get medical help or call 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 protection measures including:

- limit time in the sun, especially from 10a.m. - 2p.m.
- wear long sleeved shirts, pants, hat, and sunglasses.

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 excessive heat and direct sun.

Vanilla Mint Lip Balm SPF 30 product label

Dist. by: Raining Rose, Inc. Cedar Rapids, IA 52403

▼ PEEL HERE FOR DRUG FACTS

**Broad Spectrum SPF 30 Sunscreen
Vanilla Mint Lip Balm**

Net Wt. .15 oz.

Drug Facts

Active Ingredients:		Purpose
Avobenzene	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 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats, and sunglasses.

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 excessive heat and direct sun.

Dist. by: Raining Rose, Inc. Cedar Rapids, IA 52403

L000000

SAFETY
SEAL

avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.12 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	0.10 g in 4.25 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.25 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ROSEMARY (UNII: IJ67X351P9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0201-1	4.25 g in 1 CONTAINER; Type 0: Not a Combination Product	12/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/19/2016	

Labeler - Raining Rose, Inc. (083819404)

Registrant - Raining Rose, Inc. (083819404)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose, Inc.		083819404	manufacture(65692-0201) , label(65692-0201) , relabel(65692-0201) , repack(65692-0201)

