

SPEARMINT SPF 15 LIP - avobenzone, octinoxate, octisalate, octocrylene stick
BEESWAX SPF 15 LIP- avobenzone, octinoxate, octisalate, octocrylene stick
POMEGRANATE SPF 15 LIP- avobenzone, octinoxate, octisalate, octocrylene stick
TROPICAL SPF 15 LIP- avobenzone, octinoxate, octisalate, octocrylene stick
VANILLA SPF 15 LIP- avobenzone, octinoxate, octisalate, octocrylene 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.

PEEL HERE FOR DRUG FACTS Broad Spectrum SPF 15 Sunscreen Spearmint Lip Balm, Beeswax Lip Balm, Pomegranate Lip Balm, Tropical Lip Balm, Vanilla Lip Balm Drug Facts

Active Ingredients:

Avobenzone 2.0%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

Purpose

Sunscreen

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.

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 well with water to remove.

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*, hemp seed oil*, rosemary extract, vitamin E, aloe vera
*Certified Organic

Other Information

Protect this product from excessive heat and direct sun.

Product Label Spearmint Lip Balm Beeswax Lip Balm Pomegranate Lip Balm Tropical Lip Balm Vanilla Lip Balm

Dist. by: Raining Rose, Inc. Cedar Rapids IA 52403 L000000

PEEL HERE FOR DRUG FACTS
Broad Spectrum SPF Sunscreen

NetWt. .15 oz

Spearmint Lip Balm
Beeswax Lip Balm
Pomegranate Lip Balm
Tropical Lip Balm
Vanilla Lip Balm

▼ PEEL HERE FOR DRUG FACTS
Broad Spectrum SPF 15 Sunscreen
Spearmint Lip Balm Net Wt. .15 oz.

Drug Facts	
Active Ingredients:	Purpose
Avobenzone 2.0%	} Sunscreen
Octinoxate 6.5%	
Octisalate 5.0%	
Octocrylene 1.5%	

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

PEEL HERE FOR DRUG FACTS

Broad Spectrum SPF 15 Sunscreen

Beeswax Lip Balm

Net Wt. .15 oz.

Drug Facts

Active Ingredients:

Avobenzone 2.0%
Octinoxate 6.5%
Octisalate 5.0%
Octocrylene 1.5%

Purpose

Sunscreen

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.

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Inactive Ingredients: Sunflower oil*, beeswax, extra virgin olive oil*, 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

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▶ FEEL HERE FOR DRUG FACTS

Broad Spectrum SPF 15 Sunscreen

Pomegranate Lip Balm

Net Wt. .15 oz.

Drug Facts

Active Ingredients:

Avobenzone 2.0%
Octinoxate 6.5%
Octisalate 5.0%
Octocrylene 1.5%

Purpose

..... Sunscreen

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.

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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

PEEL HERE FOR DRUG FACTS

Broad Spectrum SPF 15 Sunscreen

Tropical Lip Balm

Net Wt. .15 oz.

Drug Facts

Active Ingredients:

Avobenzone 2.0%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

Purpose

Sunscreen

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.

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Inactive Ingredients: Sunflower oil*, beeswax, extra virgin olive oil*, flavor, hemp seed oil*, rosemary extract, vitamin E, abso vera.
*Certified Organic

Other Information

Protect this product from excessive heat and direct sun.

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

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▶ PEEL HERE FOR DRUG FACTS

Broad Spectrum SPF 15 Sunscreen

Vanilla Lip Balm

Net Wt. .15 oz.

Drug Facts

Active Ingredients:		Purpose
Avobenzone	2.0%	} Sunscreen
Octinoxate	6.5%	
Octisalate	5.0%	
Octocrylene	1.5%	

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
See Product Information for more information on the use of this product.

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

SPEARMINT SPF 15 LIP

avobenzone, octinoxate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 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	0.06 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SPEARMINT (UNII: J7I2T6IV1N)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ROSEMARY (UNII: IJ67X351P9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT (SPEARMINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0301-1	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2012	

BEESWAX SPF 15 LIP

avobenzone, octinoxate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 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	0.06 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
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1	NDC:65692-0302-1	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	12/01/2012		

POMEGRANATE SPF 15 LIP

avobenzone, octinoxate, octisalate, octocrylene stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 g in 4.25 g
	OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.21 g in 4.25 g
	OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.06 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)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	POMEGRANATE (POMEGRANATE)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0303-1	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2012	

TROPICAL SPF 15 LIP

avobenzone, octinoxate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 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	0.06 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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH (TROPICAL)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0304-1	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2012	

VANILLA SPF 15 LIP

avobenzone, octinoxate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 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	0.06 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:65692-0305-1	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product	12/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2012	

Labeler - Raining Rose, Inc. (083819404)

Registrant - Raining Rose, Inc. (083819404)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose, Inc.		083819404	manufacture(65692-0301, 65692-0305, 65692-0302, 65692-0303, 65692-0304)

Revised: 12/2017

Raining Rose, Inc.