

BROAD SPECTRUM SPF 15 SUNSCREEN FRESH BERRY LIP BALM- road spectrum spf 15 sunscreen fresh berry lip balm stick Raining Rose, Inc

Avobenzone 2.0%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

Sunscreen

For external use only

on damaged or broken skin .

Stop use and ask a doctor if rash occurs

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

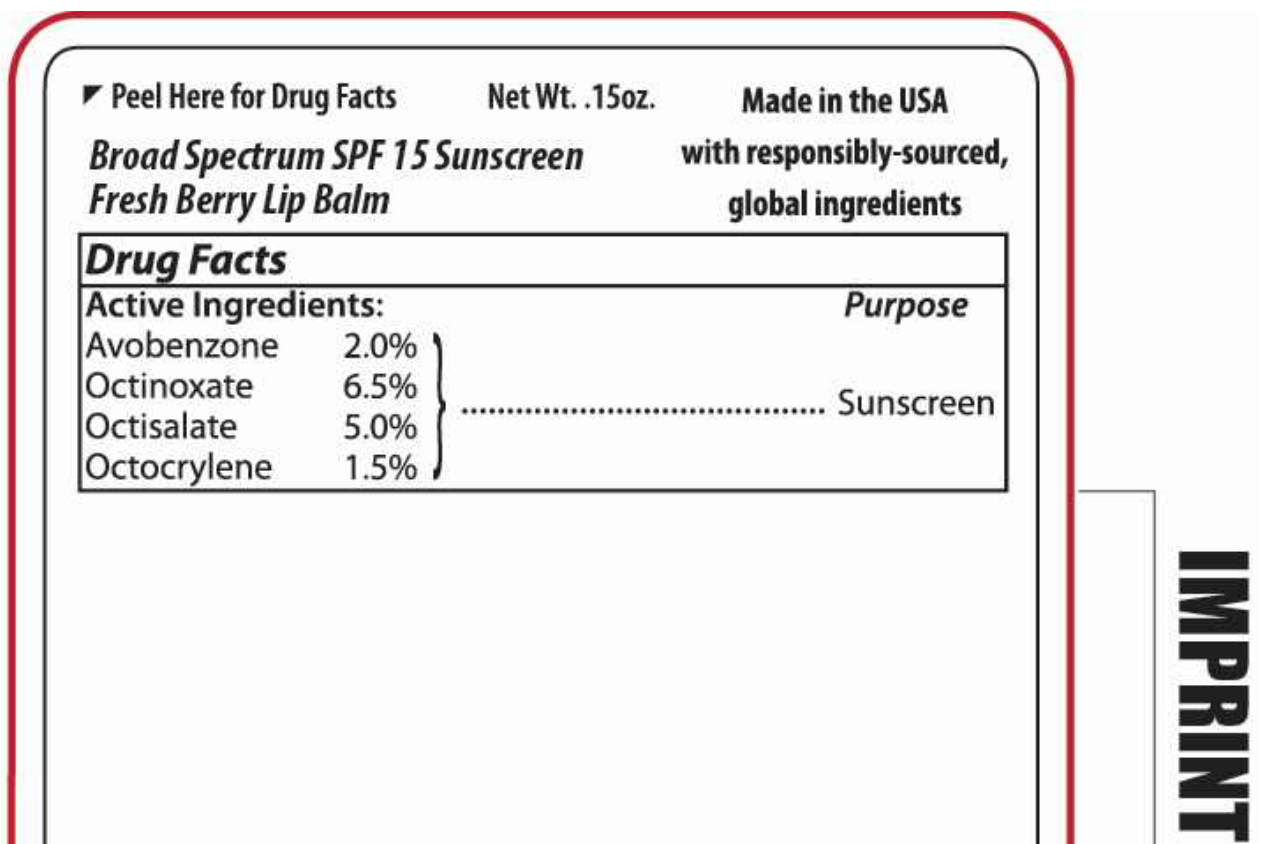
Keep out of reach of children.

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

Sunflower Oil*, Beeswax, Olive Oil*, Flavor, Hemp Seed Oil*, Rosemary Extract, Tocopherol, Soybean Oil, Sunflower Seed Oil Glycerides, Aloe Extract, Canola Oil. * Organic

Apply liberally 15 minutes before sun exposure

Helps prevent sunburn



AREA

OVERLAPPED AREA

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, Olive Oil*, Flavor, Hemp Seed Oil*, Rosemary Extract, Tocopherol, Soybean Oil, Sunflower Seed Oil Glycerides, Aloe Extract, Canola Oil. *Organic

Other Information

Protect this product from excessive heat and direct sun.

Dist. by: SmartPractice Phoenix, AZ 85008

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SAFETY SEAL

BROAD SPECTRUM SPF 15 SUNSCREEN FRESH BERRY LIP BALM

road spectrum spf 15 sunscreen fresh berry lip balm stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0576
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
CANOLA OIL (UNII: 331KBJ17RK)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL MONO/DIGLYCERIDES (UNII: HS7EB0C1ZH)	
WHITE WAX (UNII: 7G1J5DA97F)	
ROSEMARY (UNII: IJ67X351P9)	
SOYBEAN OIL (UNII: 241ATL177A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0576-1	4.25 g in 1 TUBE; Type 0: Not a Combination Product	04/23/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/23/2024	

Labeler - Raining Rose, Inc (083819404)

Registrant - Raining Rose, Inc. (083819404)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose, Inc.		083819404	manufacture(65692-0576)

