

**BREATH FRESH SPF 15 BROAD SPECTRUM LIP BALM- breath fresh spf 15  
broad spectrum lip balm stick  
Raining Rose, Inc**

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**Breath Fresh SPF 15 Lip balm**

**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:**

Sunflower Oil\*, Beeswax, Olive Oil\*, Peppermint Oil, Spearmint Oil, Hemp Seed Oil\*, Rosemary Extract, Tocopherol, Soybean Oil, Sunflower Seed Oil Glycerides, Aloe Extract, Stevia\*, Canola Oil. \* Organic

Apply liberally 15 minutes before sun exposure

Helps prevent sunburn

**Package Label**

▶ **PEEL HERE FOR DRUG FACTS**

Made in the USA

Broad Spectrum SPF 15 Sunscreen  
Breath Fresh 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, Olive Oil\*, Peppermint Oil, Spearmint Oil, Hemp Seed Oil\*, Basemery Extract, Tocopherol, Soybean Oil, Sunflower Seed Oil Glycides, Stevia\*, Aloe Extract, Canola Oil. \*Organic

**Other Information**

Protect this product from excessive heat and direct sun.

Dist. by: Company Name City State ZIP

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**SAFETY SEAL**

**BREATH FRESH SPF 15 BROAD SPECTRUM LIP BALM**

breath fresh spf 15 broad spectrum lip balm stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65692-0516
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.25 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.06 g in 4.25 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 g in 4.25 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>CANOLA OIL</b> (UNII: 331KBJ17RK)	
<b>SUNFLOWER OIL MONO/DIGLYCERIDES</b> (UNII: HS7EB0C1ZH)	
<b>STEVIA LEAF</b> (UNII: 6TC6NN0876)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0516-1	4.25 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M020	02/17/2020	

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**Labeler** - Raining Rose, Inc (083819404)

Revised: 10/2023

Raining Rose, Inc