

**ORANGE SODA SPF 15 BROAD SPECTRUM LIP BALM- orange soda spf 15
broad spectrum lip balm stick
Raining Rose, Inc**

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

Apply liberally 15 minutes before sun exposure.

Helps prevent sunburn

Package Label

DRUG FACTS

Broad Spectrum SPF 15 Sunscreen
Orange Soda Lip Balm

Drug Facts

Active Ingredients:

Avobenzone 2.0%
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 skin • Stop use and ask a doctor if you have a rash or irritation while using this product • keep out of eyes. Rinse with water if contact occurs. Keep out of reach of children. If swallowed, or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure • use as a water resistant sunscreen if swimming or sweating • Reapply every 2 hours • Children under 6 months of age: Avoid sun exposure. Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease your risk, use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun • wear long sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients: Sunflower Oil*, Beeswax, Hemp Seed Oil*, Rosemary Extract, Tocopherol, Stevia*, Jojoba Oil, Soybean Oil, Sunflower Seed Oil Glycerides.

Other Information

Protect this product from excessive heat and direct sun.

Dist. by: Company Name, City, State, Zip

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ORANGE SODA SPF 15 BROAD SPECTRUM LIP BALM

orange soda spf 15 broad spectrum lip balm stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0512
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.25 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 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

Inactive Ingredients

Ingredient Name	Strength
SOYBEAN OIL (UNII: 241ATL177A)	
STEVIA LEAF (UNII: 6TC6NN0876)	
CANOLA OIL (UNII: 331KBJ17RK)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ROSEMARY (UNII: IJ67X351P9)	
WHITE WAX (UNII: 7G1J5DA97F)	
OLIVE OIL (UNII: 6UYK2WLWLE)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL MONO/DIGLYCERIDES (UNII: HS7EB0C1ZH)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0512-1	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 Drug	M020	02/17/2020	

