

**BIG ISLAND BASICS- 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.*

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**Big Island Basics Lip Balm SPF 15 Sunscreen**

***Drug Facts***

***Active Ingredients***

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

***Purpose***

Avobenzone Sunscreen  
Octinoxate Sunscreen  
Octisalate Sunscreen  
Octocrylene Sunscreen

***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 Poison Control Center right away. **For children under 6 months of age ask a doctor before use.**

***Directions***

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating

**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 10 a.m. - 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses

***Inactive Ingredients***

Sunflower Oil\*, Beeswax, Extra Virgin Olive Oil\*, Flavor, Tocopherol, Hemp Seed Oil\*, Rosemary Leaf Extract, Aloe Vera Leaf Extract, Soybean Oil, Sunflower Seed Oil Glycerides, Canola Oil, \*Certified Organic

***Other Information:*** Protect this product from excessive heat and sun.

**Principal Display Package**

**BIG  
ISLAND**

**BASICS**

**LIP**

**BALM**

**VINTAGE PARADISE**

**NET WT .60 OZ/17G**

**For external use only**

**Broad Spectrum SPF 15 Sunscreen**

**Lip Balm**

**Made for Zodax, Panorama City, CA 91402**

**Distributed by Tommy Bahana Group, Inc. Seattle, WA 98109**

**L341677**

PEEL HERE FOR DRUG FACTS

Broad Spectrum SPF 15 Sunscreen Lip Balm



Drug Facts

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

38189103 \$ 12.50

Big Island Basics offer the essential products for a man's daily grooming.

Inspired by the tropics, Vintage Paradise SPF 15 protective lip balm is formulated with hemp seed oil and aloe leaf extract.

Reminiscent of Cuban vanilla and island rum — to make paradise a part of your daily routine.



For natural use only. For usage instructions visit us at TOMMYBAHAMA.COM

Made in the USA Tommy Bahama Group, Inc. TOMMYBAHAMA.COM

Tommy Bahama



LIP BALM

VINTAGE PARADISE

NET WT .60 OZ / 17g

Drug Facts (continued)

Uses Helps prevent sunburn

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Other Information

Protect this product from excessive heat and direct sun.

Made for Tommy Bahama by Zedax Panorama City, CA 91402 Distributed by Tommy Bahama Group, Inc. Seattle, WA 98109

L337995

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BIG ISLAND BASICS

avobenzone, octinoxate, octisalate, octocrylene stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65692-1005
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	65 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	15 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>SUNFLOWER OIL MONOGLYCERIDES</b> (UNII: ZVW8EIZ3IE)	
<b>CANOLA OIL</b> (UNII: 331KBJ17RK)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65692-1005-1	17 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2020	

**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 final	part352	04/01/2020	

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