

**VACATION LIP TRIPS DESSERTS- avobenzene, homosalate, octisalate, and octocrylene  
Vacation 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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**Vacation® Lip Trips Desserts**

**Drug Facts**

**Active ingredients**

Avobenzene (3%), Homosalate (5%), Octisalate (3%), Octocrylene (10%)

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

**For external use only**

- **Do not use** on damaged or broken skin
- **When using this product**, keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor if** rash occurs
- **Keep out of reach of children.** In case of ingestion, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally 15 minutes before sun exposure.
- Reapply: after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses children under 6 months of age: ask a physician.

## **Other information**

- Protect this product from excessive heat and direct sun

## **Inactive ingredients**

Aloe Barbadensis (Aloe Vera) Leaf Extract, Butyloctyl Salicylate, C18-38 Alkyl Hydroxystearoyl Stearate, Canola Oil, Cocos Nucifera (Coconut) Oil, Euphorbia Cerifera (Candelilla) Wax, Flavor, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Seed Wax, Olea Europaea (Olive) Fruit Oil, Ricinus Communis (Castor) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Stevia Rebaudiana Leaf Extract, Sunflower Seed Oil Glycerides, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol (Vitamin E), Tocopheryl Acetate

Distributed by Vacation Inc.

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

5 TUBE COLLECTER'S SET

VACATION®

LIP TRIPS:

Desserts

SPF 30 SUNSCREEN LIP BALM

BROAD SPECTRUM SPF 30 | VEGAN & CRUELTY FREE  
WATER RESISTANT (80 MINUTES)

5 - 0.15 OZ (4.25 G) BALMS

TOTAL NET WT. 0.75 OZ (21.25 G)





## VACATION LIP TRIPS DESSERTS

avobenzone, homosalate, octisalate, and octocrylene kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80641-201
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80641-201-01	1 in 1 CARTON	01/15/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	4.25 g
Part 2	1 TUBE	4.25 g
Part 3	1 TUBE	4.25 g
Part 4	1 TUBE	4.25 g
Part 5	1 TUBE	4.25 g

### Part 1 of 5

## VACATION LIP TRIPS DESSERTS PINEAPPLE UPSIDE DOWN CAKE

avobenzone, homosalate, octisalate, and octocrylene stick

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.03 g in 1 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>C18-38 Alkyl Hydroxystearoyl Stearate</b> (UNII: WW4FVB2PEM)	
<b>Canola Oil</b> (UNII: 331KB17RK)	
<b>Coconut Oil</b> (UNII: Q9L0073W7L)	
<b>Candelilla Wax</b> (UNII: WL0328HX19)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Helianthus Annuus Seed Wax</b> (UNII: 42DG15CHXV)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Castor Oil</b> (UNII: D5340Y2I9G)	
<b>Rosemary</b> (UNII: IJ67X351P9)	
<b>Jobba Oil</b> (UNII: 724GKU717M)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Cocoa Butter</b> (UNII: 512OYT1CRR)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/15/2022	

## Part 2 of 5

### VACATION LIP TRIPS DESSERTS BOMBE ALASKA

avobenzene, homosalate, octisalate, and octocrylene stick

#### Product Information

**Route of Administration** TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzene</b> (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	0.03 g in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.03 g in 1 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>C18-38 Alkyl Hydroxystearoyl Stearate</b> (UNII: WW4FVB2PEM)	
<b>Canola Oil</b> (UNII: 331KBJ17RK)	
<b>Coconut Oil</b> (UNII: Q9L0O73W7L)	
<b>Candelilla Wax</b> (UNII: WL0328HX19)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Helianthus Annuus Seed Wax</b> (UNII: 42DG15CHXV)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Castor Oil</b> (UNII: D5340Y2I9G)	
<b>Rosemary</b> (UNII: IJ67X351P9)	
<b>Jobba Oil</b> (UNII: 724GKU717M)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Cocoa Butter</b> (UNII: 512OYT1CRR)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

#### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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**Part 3 of 5****VACATION LIP TRIPS DESSERTS AFTER DINNER MINT**

avobenzene, homosalate, octisalate, and octocrylene stick

**Product Information****Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Avobenzene</b> (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	0.03 g in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.03 g in 1 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>C18-38 Alkyl Hydroxystearoyl Stearate</b> (UNII: WW4FVB2PEM)	
<b>Canola Oil</b> (UNII: 331KBj17RK)	
<b>Coconut Oil</b> (UNII: Q9L0073W7L)	
<b>Candelilla Wax</b> (UNII: WL0328HX19)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Helianthus Annuus Seed Wax</b> (UNII: 42DG15CHXV)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Castor Oil</b> (UNII: D5340Y2I9G)	
<b>Rosemary</b> (UNII: IJ67X351P9)	
<b>Jjoba Oil</b> (UNII: 724GKU717M)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Cocoa Butter</b> (UNII: 512OYT1CRR)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/15/2022	

## Part 4 of 5

### VACATION LIP TRIPS DESSERTS STRAWBERRY JELLO

avobenzone, homosalate, octisalate, and octocrylene stick

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.03 g in 1 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>C18-38 Alkyl Hydroxystearoyl Stearate</b> (UNII: VVW4FVB2PEM)	
<b>Canola Oil</b> (UNII: 331KBJ17RK)	
<b>Coconut Oil</b> (UNII: Q9L0O73W7L)	
<b>Candelilla Wax</b> (UNII: WL0328HX19)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Helianthus Annuus Seed Wax</b> (UNII: 42DG15CHXV)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Castor Oil</b> (UNII: D5340Y2I9G)	
<b>Rosemary</b> (UNII: IJ67X351P9)	
<b>Jjoba Oil</b> (UNII: 724GKU717M)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Cocoa Butter</b> (UNII: 512OYT1CRR)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

## Packaging



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/15/2022	

## Part 5 of 5

### VACATION LIP TRIPS DESSERTS BANANAS FOSTER

avobenzone, homosalate, octisalate, and octocrylene stick

## Product Information

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.05 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.03 g in 1 g
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>C18-38 Alkyl Hydroxystearoyl Stearate</b> (UNII: WW4FVB2PEM)	
<b>Canola Oil</b> (UNII: 331KBJ17RK)	
<b>Coconut Oil</b> (UNII: Q9L0O73W7L)	
<b>Candelilla Wax</b> (UNII: WL0328HX19)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Helianthus Annuus Seed Wax</b> (UNII: 42DG15CHXV)	
<b>Olive Oil</b> (UNII: 6UYK2W1W1E)	
<b>Castor Oil</b> (UNII: D5340Y2I9G)	
<b>Rosemary</b> (UNII: IJ67X351P9)	
<b>Jobba Oil</b> (UNII: 724GKU717M)	
<b>Stevia Rebaudiuna Leaf</b> (UNII: 6TC6NN0876)	
<b>Cocoa Butter</b> (UNII: 512OYT1CRR)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/15/2022	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/15/2022	

**Labeler** - Vacation Inc. (117644631)**Establishment**

Name	Address	ID/FEI	Business Operations
Raining Rose		083819404	MANUFACTURE(80641-201)

Revised: 1/2022

Vacation Inc.