#### FOREVER SUN LIPS- sunscreen lipstick Aloe Vera of America, 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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#### Forever Sun Lips

Active Ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 10.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 2.79%	Sunscreen
Petrolatum 38%	Lip Protectant

#### Uses

- helps prevent and temporarily protects chapped or cracked lips
- helps prevent and protect from the drying effects of wind and cold weather
- 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 and broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if rash occurs

**Keep out of reach of children.** If product is swallowed, 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 this 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: Ask a doctor

#### **Inactive ingredients**

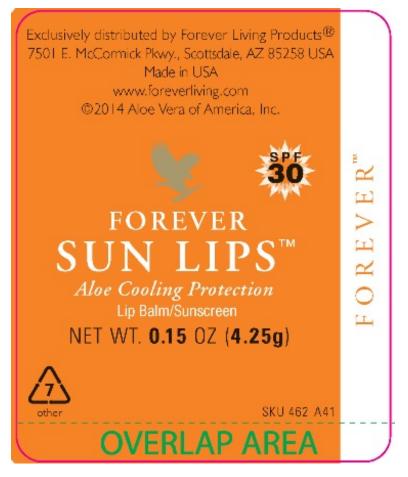
glycine soja (soybean) oil, ozokerite, butyloctyl salicylate, flavor, beeswax, ethylhexyl hydroxystearate, euphorbia cerifera (candelilla) wax, simmondsia chinensis (jojoba) seed oil, copernicia cerifera (carnauba) wax, menthol, menthyl lactate, aloe barbadensis leaf extract, allantoin

#### Other information

• protect this product from excessive heat and direct sun

#### **Questions or comments?**

Call 1-888-440-2563







### FOREVER SUN LIPS

sunscreen lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11697-462
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.1275 g in 4.25 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	$0.4250 \ g$ in $4.25 \ g$	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	$0.2125 \ g$ in $4.25 \ g$	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	$0.1186 \ g$ in $4.25 \ g$	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1.6150 g in 4.25 g	

#### **Inactive Ingredients**

Ingredient Name	Strength
SO YBEAN OIL (UNII: 241ATL177A)	.4473 g in 4.25 g
CERESIN (UNII: Q1LS2UJO3A)	.3868 g in 4.25 g
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	.2295 g in 4.25 g
YELLOW WAX (UNII: 2ZA36H0S2V)	.1275 g in 4.25 g
ETHYLHEXYL HYDROXYSTEARATE (UNII: B7I80BVV5E)	.1148 g in 4.25 g
CANDELILLA WAX (UNII: WL0328HX19)	.1063 g in 4.25 g
JOJOBA OIL (UNII: 724GKU717M)	.0850 g in 4.25 g
CARNAUBA WAX (UNII: R12CBM0EIZ)	.0425 g in 4.25 g
MENTHOL (UNII: L7T10EIP3A)	.0223 g in 4.25 g

MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	.0223 g in 4.25 g
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	.0138 g in 4.25 g
ALLANTO IN (UNII: 344S277G0Z)	.0004 g in 4.25 g

Packaging				
# Item Code	Package Description	Marketing	Start Date	Marketing End Date
<b>1</b> NDC:11697-462-03	12 in 1 BOX			
<b>1</b> NDC:11697-462-02	1 in 1 CARTON			
<b>1</b> NDC:11697-462-01	4.25 g in 1 TUBE			
Marketing Info	rmation			
Marketing Info Marketing Category	rmation Application Number or Monog	raph Citation	Marketing Start Da	nte Marketing End Date

# Labeler - Aloe Vera of America, Inc. (049049463)

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Aloe Vera of America, Inc.		049049463	manufacture(11697-462)

Revised: 3/2014

Aloe Vera of America, Inc.