

**ACAIFUSION LIP BALM BROAD SPECTRUM SPF 30 SUPERGOOP- avobenzone, octinoxate, octisalate ointment  
SUPERGOOP LLC**

*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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**Acaifusion Lip Balm Broad Spectrum SPF 30**

Active Ingredients	Purpose
Avobenzone 3%, Octinoxate 7.5%, Octisalate 5%	Sunscreen

**Uses**

- Helps prevent and temporarily chafed, chapped, cracked, or windburned skin and/or lips.
- 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
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.
- Stop use and ask a doctor if rash occurs

**Warnings**

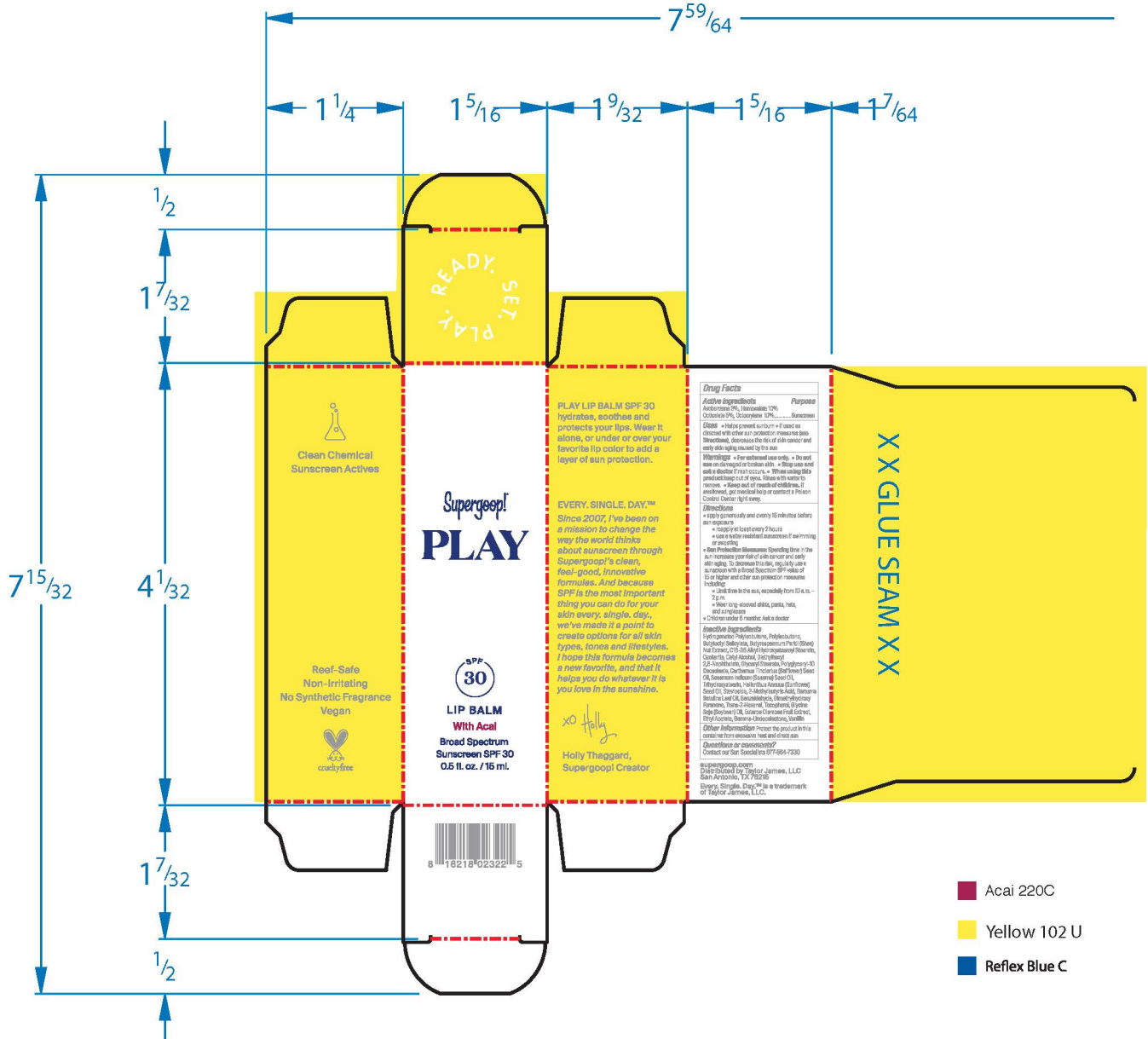
- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.

**Directions**

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

Inactive Ingredients-Petrolatum, Ozokerite, Beeswax, Polyester-7, Neopentyl Glycol Diheptanoate, Flavor, Sorbitan Oleate, Euphorbia Cerifera (Candelilla) Wax, Polysilicone-15, Glycine Soja (Soybean) Oil, Tocopherol, Butyrospermum Parkii (Shea) Butter, Honey, Ascorbyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Aloe Barbadosis Leaf Extract, Ricinus Communis (Castor) Seed Oil, Red 27 Lake, Cocos Nucifera (Coconut) Fruit Extract

# Play Lip Balm SPF 30 with Acai



- Acai 220C
- Yellow 107C
- Reflex Blue C

PARTIAL LARGE SIZE  
**200%**



	<b>FILE INFORMATION</b>		<b>PROJECT INFORMATION</b>		<b>CLIENT APPROVAL CHECKLIST</b>	
	FILE NAME	T-19	TUBE DIAMETER	19 mm	<input type="checkbox"/> DieLine <input type="checkbox"/> Copy <input type="checkbox"/> Colors <input type="checkbox"/> UPC <input type="checkbox"/> Photography <input type="checkbox"/> Illustration <input type="checkbox"/> Eye Mark	
CLIENT	customer code	TUBE LENGTH	80 mm	<input type="checkbox"/> Silver <input type="checkbox"/> Gold <input type="checkbox"/> Other Metallic Color		
STARTED	06/11/09 CGP	<b>PRINT INFORMATION</b>		<input type="checkbox"/> 5 mm unvarnished from bottom		
MODIFIED	00/00/00 CGP	OFFSET	COLOR	<b>INTERNAL APPROVAL</b> Design: <i>Ye</i> Proof: _____ UPC Test: _____   Verify: _____		
SOFTWARE	ai by Illustrator CS cdr by Coreldraw 9	SILK-SCREEN	COLOR	RELEASE DATE: _____ <input type="checkbox"/> TUBE COLOR <input checked="" type="checkbox"/> DIELINE DOES NOT PRINT		
PROOF NUMBER	1	EXPORT	PDF	client signature: _____ date: _____ <b>IMPORTANT: This art has been checked and proofed for accuracy. It is the responsibility of the client to make all final approvals before the release of this art. PLEASE DOUBLE CHECK FOR ACCURACY.</b>		
PROOF SIZE	100%					

## ACAIFUSION LIP BALM BROAD SPECTRUM SPF 30 SUPERGOOP

avobenzone, octinoxate, octisalate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75936-118
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.44 g in 15 mL

<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.11 g in 15 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.74 g in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>COCONUT</b> (UNII: 3RT3536DHY)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>POLYSILICONE-15</b> (UNII: F8DRP5BB29)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>HONEY</b> (UNII: Y9H1V576FH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-118-02	1 in 1 BOX	06/28/2012	
1	NDC:75936-118-01	15 mL 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	06/28/2012	

**Labeler** - SUPERGOOP LLC (117061743)