

**GAP FAVORITE LIP BALM GREEN APPLE SPF 18- octinoxate and oxybenzone stick**  
**Autumn Harp, 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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**Drug Facts**

**Active Ingredient**

Active Ingredient	Purpose
Octinoxate 7.5%	Sunscreen
Oxybenzone 6%	Sunscreen

**Purpose**

- lip moisturizer
- helps prevent sunburn
- higher SPF gives more sunburn protection

**Warning**

**Warnings**

For external use only.

**When using this product**

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

**Stop use**

Stop use and ask doctor if rash and irritation develops and lasts

**Keep out of reach of children**

Keep out of reach of children. If swallowed get medical help or contact Poison Control right away.

**Directions**

- apply liberally before sun exposure and as needed
- children under 6 months of age: ask a doctor

**Sun Alert**

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin cancer, and other harmful effects of the sun.

**Inactive Ingredients**

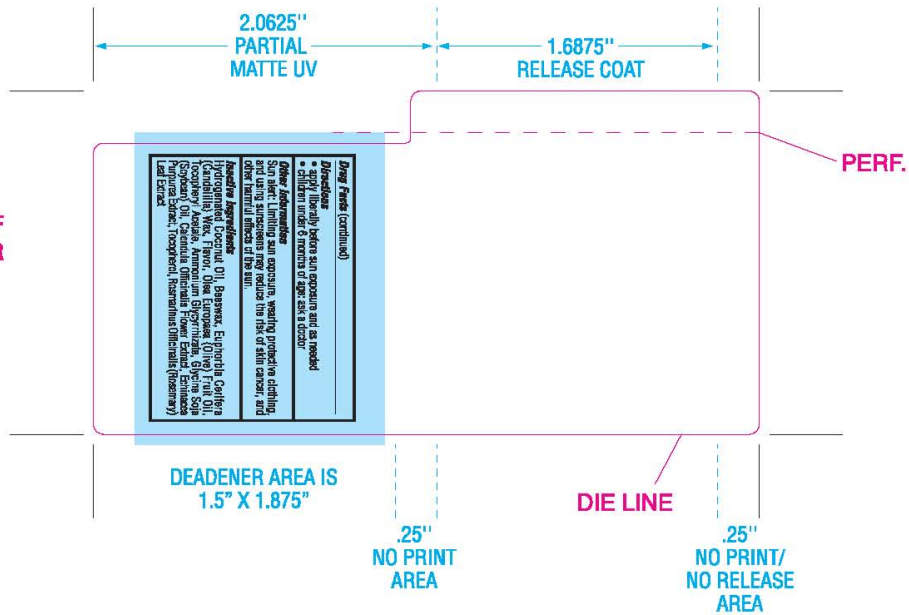
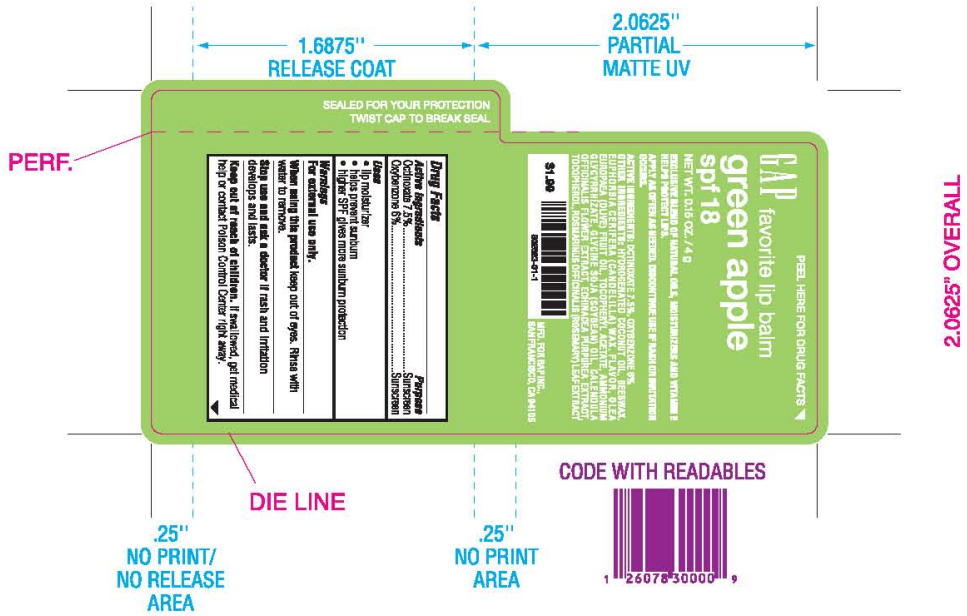
**Inactive Ingredients:** Hydrogenated Coconut Oil, Beeswax, Euphorbia Cerifera (Candelilla) Wax,

Flavor, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Ammonium Glycyrrhizate, Glycine Soja (Soybean) Oil, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Tocopherol, Lecithin, Rosmarinus Officinalis (Rosemary) Leaf Extract.

**Label**

M62828

4.0" OVERALL



GAP FAVORITE LIP BALM GREEN APPLE SPF 18

octinoxate and oxybenzone stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51514-0223
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ROSEMARY (UNII: IJ67X351P9)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	APPLE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0223-1	4 g in 1 CONTAINER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/06/2011	

**Labeler** - Autumn Harp, Inc (064187883)

**Establishment**

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc		064187883	manufacture

Revised: 12/2011

Autumn Harp, Inc