

**GAP FAVORITE LIP BALM STRAWBERRY KIWI- 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.*

-----

**DRUG FACTS**

**ACTIVE INGREDIENTS**

Active Ingredients	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 a 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**

Directions:

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

**Sun Alert**

Other information

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**



octinoxate and oxybenzone stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51514-0213
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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

<b>Ingredient Name</b>	<b>Strength</b>
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
TOCOPHEROL (UNII: R0ZB2556P8)	
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>	STRAWBERRY (STRAWBERRY KIWI)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0213-1	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	11/17/2011	

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

**Establishment**

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

Revised: 11/2011

Autumn Harp, Inc