# GAP FAVORITE LIP BALM BERRY PUNCH SPF 18 - octinoxate and oxybezone 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 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 tis product

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

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

#### Sun Alert

Other information

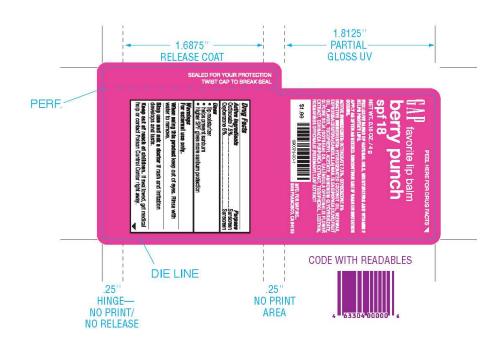
Sun alert: limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin cancer, and other harmful effects of the sun.

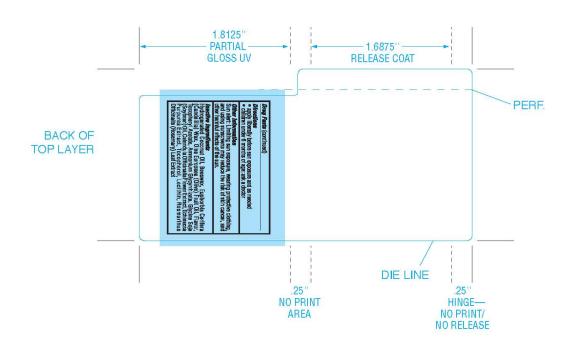
**Inactive Ingredients:** Hydrogenated Coconut Oil, Beeswax, Euphorbia Cerifera (Candelilla) Wax, Olea Europaea (Olive) Fruit Oil, Flavor, Tocopheryl Acetate, Ammonium Glycyrrhizate, Glycine Soja (Soybean) Oil, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Tocopherol,

Lecithin, Rosmarinus Officinalis (Rosemary) Leaf Extract.

Label

#### M66233





octinoxate and oxybezone stick

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51514-0217
Route of Administration	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: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
HYDROGENATED COCONUT OIL (UNII: JY810XM10M)	
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: 4N9 P6 CC1DX)	
AMMO NIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0217-1	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	11/21/2011	

# Labeler - Autumn Harp, Inc (064187883)

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

Revised: 11/2011 Autumn Harp, Inc