

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.

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

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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	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: 4N9P6CC1DX)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	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