GAP FAVORITE LIP BALM CITRUS SPLASH 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.

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

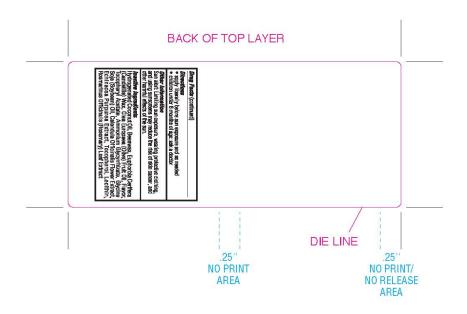
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin cancer, and other harmful effects of the sun.

Inactive Ingredients

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

M65149





octinoxate and oxybenzone stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0212
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:950OS7VE0Y)	OXYBENZONE	6 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
HYDROGENATED COCONUT OIL (UNII: JY810XM10M)	
OLIVE OIL (UNII: 6 UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328 HX19)	
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	GRAPEFRUIT (Grape fruit Lime)	Imprint Code
Contains		

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0212-1	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	11/16/2011	

Labeler - Autumn Harp, Inc (064187883)

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

Revised: 11/2011 Autumn Harp, Inc