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

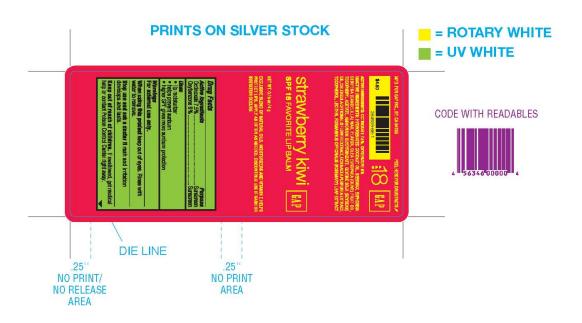
Other information

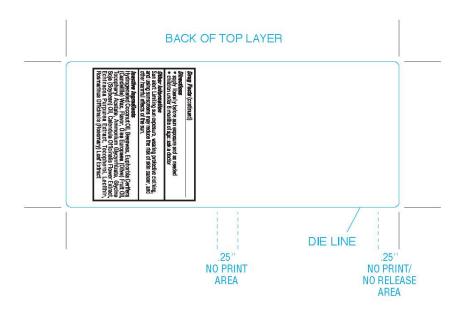
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin cancer, and other harmfu; effects of the sun.

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	Pro	duct	Info	rma	tior
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:51514-0213

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y) OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y) OXYBENZONE

Inactive Ingredients				
Ingredient Name	Strength			
HYDROGENATED CO CO NUT O IL (UNII: JY8 10 XM10 M)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
CANDELILLA WAX (UNII: WL0328HX19)				
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ROSEMARY (UNII: IJ67X351P9)				
ECHINACEA, UNSPECIFIED (UNII: 4N9 P6 CC1DX)				
AMMO NIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	STRAWBERRY (STRAWBERRY KIWI)	Imprint Code		
Contains				

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