

**GAP FAVORITE LIP BALM APPLE PIE 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.*

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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 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**

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

**Sun Alert**

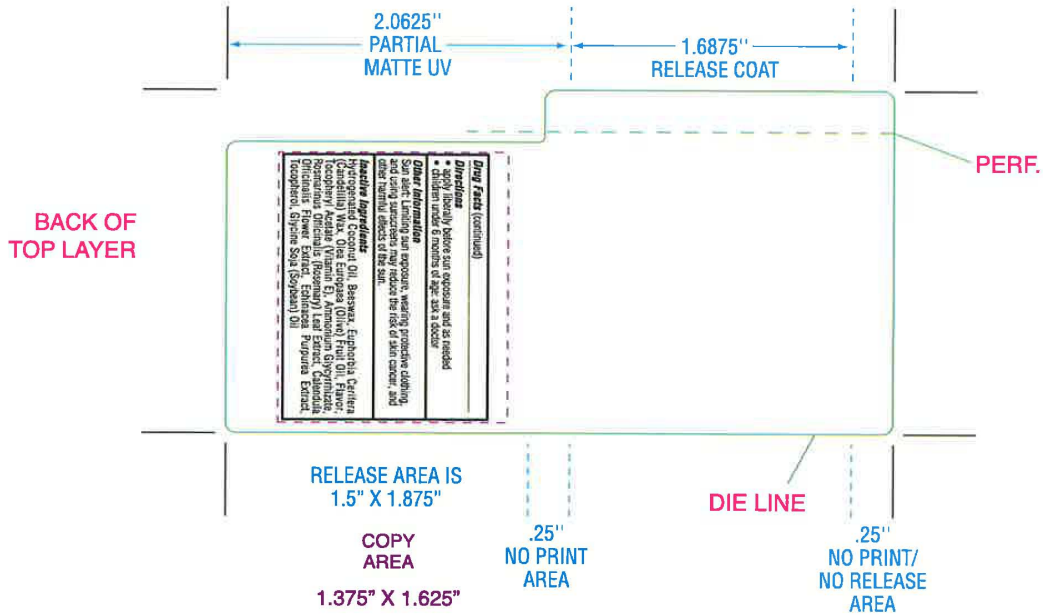
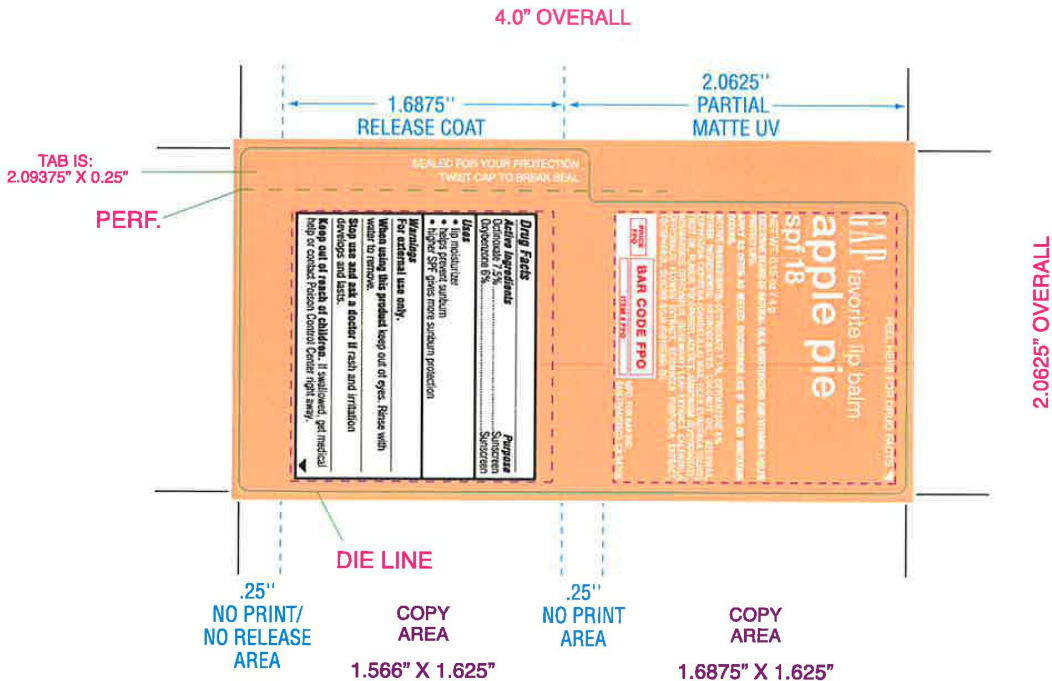
Other information

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**

Enter section text here

label



INTER PARFUMS USA, LLC | CREATIVE

FILE NAME: GapOutlet.LipBalm.ApplePie	BRAND: GAP OUTLET
ARTIST: TONI-MARIE FIGUEROA	DESCRIPTION: GAP OUTLET DRUG FACT LABEL
DATE OF THIS VERSION: 04.07.2010 REVISED: 4.27.10	RELEASE DATE: 4.27.2010

4.27.2010

ART DIRECTOR	MARKETING DEPARTMENT
<i>[Signature]</i>	
APPROVAL SIGN-OFFS	



ALL DECO PRINTS ON WHITE LABEL STOCK  
ALL WHITE IS KNOCK-OUT  
DRUG FACTS / BARCODE PRINT BLACK

# GAP FAVORITE LIP BALM APPLE PIE SPF 18

octinoxate and oxybenzone stick

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0227
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: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
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)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ROSEMARY (UNII: IJ67X351P9)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0227-1	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	12/08/2011	

Labeler - Autumn Harp, Inc (064187883)

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## Establishment

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

Revised: 12/2011

Autumn Harp, Inc