

GAP FAVORITE LIP BALM VANILLA MINT SPF - 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 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

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

Fragrance, 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 oxybenzone stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51514-0215 |
| 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 | VANILLA (VANILLA MINT) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51514-0215-1 | 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.