

LIP CARE SPF 15 WITH VITAMIN E- octinoxate, 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.

LIP CARE SPF 15 WITH VITAMIN E

Drug Facts

☐Active Ingredient

Octinoxate (7.5% w/w)

Oxybenzone (5.0% w/w)

☐Purpose

Sunscreen

Sunscreen

☐Uses

- Helps prevent sunburn

☐Warnings

• **Skin Cancer/Skin Aging Alert** ☐Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, skin cancer or early skin aging.

- **For external use only.**

Don not use • on damaged or broken skin.

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- ☐rash occurs.

Keep out of reach of children. ☐If product is swallowed, get medical help or contact a Poison Control Center right away.

☐Directions

- Apply liberally 15 minutes before sun exposure.
- reapply this product at least every 2 hours.
- use water resistant sunscreen if swimming or sweating.
- children under 6 months of age: ask a doctor.

Other information

- protect the product in this container from excessive heat and direct sun.

Inactive Ingredients:

Ricinus Communis (Castor) Seed Oil, Hydrogenated Coconut Oil, Olea Europaea (Olive) Fruit Oil, Beeswax, Euphorbia Cerifera (Candelilla) Wax, Cocos Nucifera (Coconut) Oil, Tocopheryl Acetate, Vanilla Planifolia Extract, Ammonium Glycyrrhizate, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Tocopherol, Glycine Soja (Soybean) Oil.

Principal Display Panel

Image Components



LIP CARE SPF 15 WITH VITAMIN E

octinoxate, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0336
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	5.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
VANILLA (UNII: Q74T35078H)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0336-1	4.2 g in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/20/2004	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0336)