

**VITAMIN E SPF15 LIP BALM- avobenzone, octisalate, octocrylene stick
Autumn Harp, Inc.**

Lip Care SPF 15 With Vitamin E

Drug Facts

Active Ingredient

Avobenzone (2.0%, w.w)

Octisalate (5.0%, w.w)

Octocrylene (3.0%, w/w)

Purpose

Sunscreen

Sunscreen

Sunscreen

Uses

* helps prevent sunburn

Warnings

- For **external use only**

Do 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.

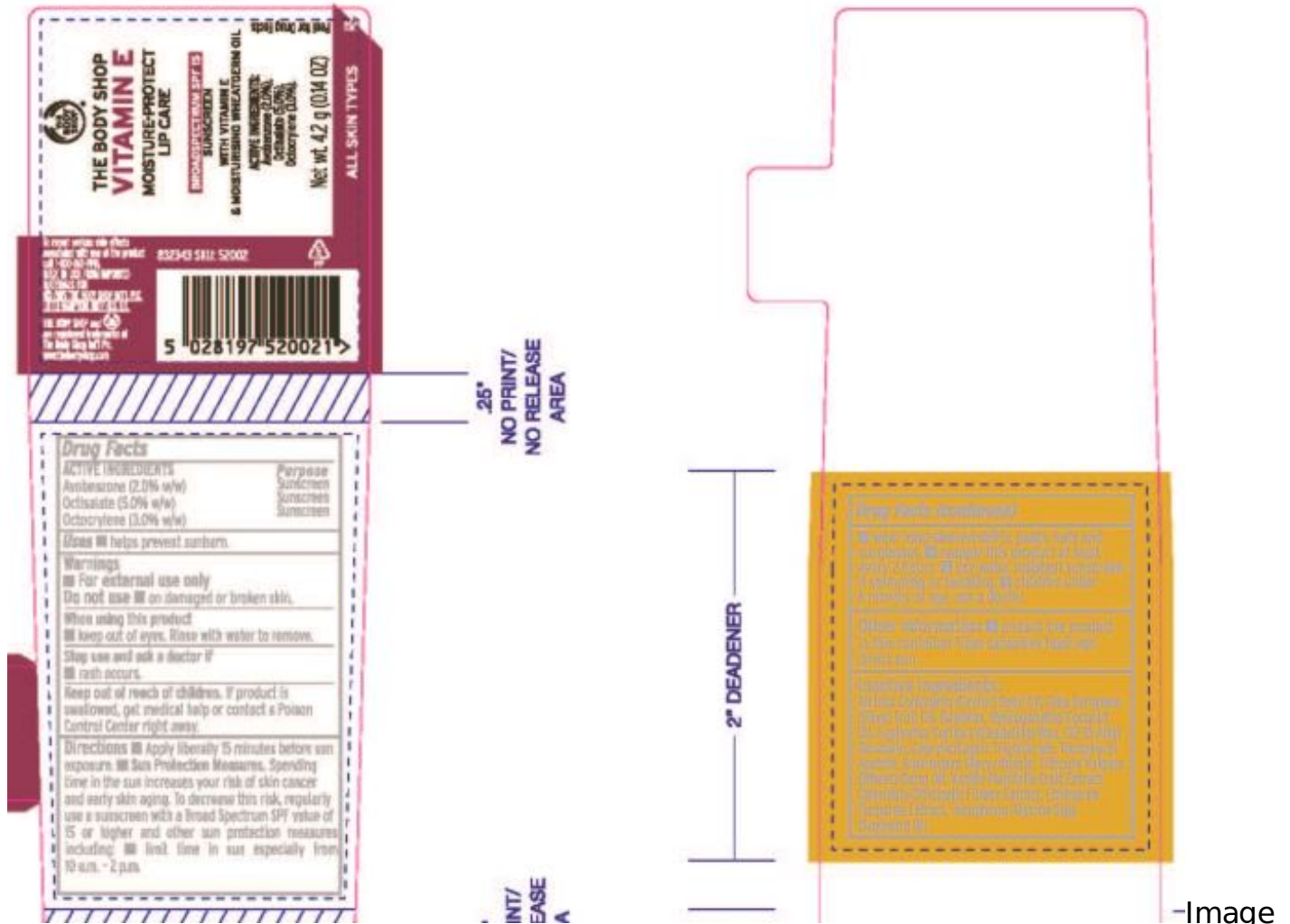
Directions • Apply liberally 15 minutes before sun exposure. • **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in sun especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses. • 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, Olea Europaea (Olive) Fruit Oil, Beeswax, Hyrdogenated Coconut Oil, Euphorbia Cerifera (Candelilla) Wax, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Tocopheryl Acetate, Ammonium Glycyrhizate, Triticum Vulgare (Wheat) Germ Oil, Vanilla Planifolia Fruit Extract (Vanilla), Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Tocopherol, Glycine Soja (Soybean) Oil

Principal Display Panel



components

VITAMIN E SPF15 LIP BALM			
avobenzone, octisalate, octocrylene stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0342
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
WHEAT GERM OIL (UNII: 14C97E680P)	
VANILLA (UNII: Q74T35078H)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SOYBEAN OIL (UNII: 241ATL177A)	
CANDELILLA WAX (UNII: WL0328HX19)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0342-1	4.2 g in 1 CYLINDER; Type 0: Not a Combination Product	03/13/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/13/2013	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0342)

Revised: 1/2023

Autumn Harp, Inc.