

VITAMIN E MOISTURE-PROTECT LIP CARE SPF 15- octisalate, avobenzone, and octocrylene stick

The Body Shop, Wake Forest

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.

VITAMIN E MOISTURE-PROTECT LIP CARE SPF 15

Drug Facts

ACTIVE INGREDIENTS	<i>Purpose</i>
Avobenzone (2.0% w/w)	Sunscreen
Octisalate (5.0% w/w)	Sunscreen
Octocrylene (3.0% w/w)	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, Hydrogenated Coconut Oil, Euphorbia Cerifera (Candelilla) Wax, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Tocopheryl Acetate, Ammonium Glycyrrhizate, Triticum Vulgare (Wheat) Germ Oil, Vanilla Planifolia Fruit Extract, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Tocopherol, Glycine Soja (Soybean) Oil.

PRINCIPAL DISPLAY PANEL - 4.2 g Container

**THE
BODY
SHOP®**

**THE BODY SHOP
VITAMIN E
MOISTURE-PROTECT
LIP CARE**

**BROADSPECTRUM SPF 15
SUNSCREEN**

**WITH VITAMIN E
& MOISTURISING WHEATGERM OIL**

ACTIVE INGREDIENTS:

Avobenzone (2.0%),
Octisalate (5.0%),
Octocrylene (3.0%).

Net wt. 4.2 g (0.14 OZ)

ALL SKIN TYPES

Peel for Drug Facts

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VITAMIN E
MOISTURE-PROTECT
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 15 or higher and other sun protection measures
 including ■ limit time in sun especially from
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Do not use within 48 hours after
 cosmetic laser treatment.
 Do not use within 48 hours after
 chemical peel.
 Do not use within 48 hours after
 waxing.
 Do not use within 48 hours after
 electrolysis.
 Do not use within 48 hours after
 laser treatment.
 Do not use within 48 hours after
 microdermabrasion.
 Do not use within 48 hours after
 retinoid treatment.
 Do not use within 48 hours after
 tanning bed use.
 Do not use within 48 hours after
 tanning lotion use.
 Do not use within 48 hours after
 tanning spray use.
 Do not use within 48 hours after
 tanning booth use.
 Do not use within 48 hours after
 tanning bed use.
 Do not use within 48 hours after
 tanning lotion use.
 Do not use within 48 hours after
 tanning spray use.
 Do not use within 48 hours after
 tanning booth use.

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 10000 W. 16th Ave., Golden, CO 80401
 www.thebodyshop.com

Peel for Drug Facts

Drug Facts (continued)

■ wear sun-protective 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 this product
 in this container from excessive heat and
 direct sun.

Inactive ingredients:
 Bisone Emulsion (Water), Bees Wax, Emulsion
 (Olive) Fruit Oil, Benzoin, Hydroxyethyl Cocoyl
 Oil, Eucalyptus Globulus Essential Oil, C12-15 Alkyl
 Benzoate, Caprylic/Capric Triglyceride, Tocopheryl
 Acetate, Ammonium Glycyrrhizate, Hibiscus Hydrate
 (Seed), Iron Oxide (Black), Iron Oxide (Red),
 Carotenes (Orange), Flax Seed Extract, Estemone
 Precious Flower, Squalene, Spice Oil,
 (Soybean) Oil.

VITAMIN E MOISTURE-PROTECT LIP CARE SPF 15			
octisalate, avobenzone, and octocrylene stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57691-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)		Octisalate	0.05 g in 1 g
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)		Avobenzone	0.02 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)		Octocrylene	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
Hydrogenated Coconut Oil (UNII: JY81OXM1OM)	
CANDELILLA WAX (UNII: WL0328HX19)	
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: P0M704Y7YD)	
Echinacea Purpurea (UNII: Q17G114Y98)	
Tocopherol (UNII: R0ZB2556P8)	
SOYBEAN OIL (UNII: 241ATL177A)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57691-002-42	4.2 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/14/2016	

Labeler - The Body Shop, Wake Forest (791071279)

Revised: 3/2016

The Body Shop, Wake Forest