# GOLFERSSKIN SUNSCREEN LIP BALM - avobenzone, octinoxate, octocrylene stick Skin Alive, Ltd.

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.

-----

## Golfers Skin Sunscreen Lip Balm

Active Ingredients Avobenzone 2.5% Octinoxate 7.5% Octocrylene 5.0%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Higher SPF gives more sunburn protection

Provides high protection against sunburn

Retains SPF after 80 minutes of sweating.

Warnings

For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing and using a sunscreen.

When using this product

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if irritation occurs or rash develops and lasts.

Keep out of reach of children.

Directions

Apply generously 15 mins before sun exposure and as needed

Children under 6 months of age; ask a doctor

Reapply as needed or after towel drying, swimming or sweating.

**Inactive Ingredients** 

Aloe vera, Beeswax, Capryllic/Capric Triglyceride, Castor Oil, Jojoba Oil, Lanolin, Tocopheryl Acetate, Vanilla lip

Golfers Skin SPF 30+ Sunscreen Lip Balm moisturizes lips with Vitamin E and Aloe Vera

To report a serious adverse event, contact 1-800-332-1088

Expires:

Lot Number:

www.golfersskin.co

DIST. BY Quiver Dist, Bend Oregon, USA 97701

AS/ANZ STANDARD 2604-1998

Tested on Golfers - Not Animals

Net Wt. .3oz (8.5g)

SPF 30+

very water / sweat resistant

broad spectrum

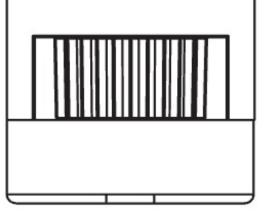
UVA/UVB protection

Proven in extreme New Zealand conditions Golfers Skin sunscreen lip balm

Net Wt. .30 oz (8.5g)

contains no nanoparticles - aminobenzoic acid (PABA)-free





Golfersskin SPF 30+ Sunscreen Lip Balm moisturizes lips with vitamin E and Aloe Vera.





www.golfersskin.co





#### Drug Facts

(continued).

#### Directions

- Apply generously 15mins before sun exposure and as needed.
- Children under 6months of age:ask a doctor.
- Reapply as needed or after towel drying, swimming, or sweating.

#### Inactive Ingredients

AloeVera, Beeswax, Capryllic/Capric Triglyceride, Castor Oil, Jojoba Oil, Lanolin, Tocopheryl Acetate, Vanilla lip.

To report a serious adverse event, contact 1-800-332-1088

LOT NUMBER :



Net Wt. .30 oz (8.5g)

CONTAINS NO NANOPARTICLES - AMINOBENZOIC ACID(PABA) - FREE



- sweat resistant
- broad spectrum
- UVA / UVB protection





www.golfersskin.co

Golfers Skin SPF 30+ Sunscreen Lip Balm moisturizes lips with vitamin E and Aloe Vera.

### Drug Facts

Octocrylene 5.0%

#### Active Ingredients

Avobenzone 2.5% Octinoxate 7.5%

Sunscreen

Purpose

#### Uses

Helps prevent sunburn.

·Higher SPF gives more sun burn protection. Provides high protection against sunburn. Retains SPF after 80 minutes of sweating.

#### Warnings

For External use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging & other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, & using a sunscreen.

When using this product

Keep out of eyes. Rinse with water to remove

Stop use and ask a Doctor if Irritation occurs or rash developes and lasts

Keep out of reach of children.

### www.golfersskin.co

DIST. BY Quiver Dist., Bend Oregon, USA 97701 AS/ANZ STANDARD 2604:1998 Tested on Golfers - Not Animals

Strength

Net Wt. .30 oz (8.5q)

### **GOLFERSSKIN SUNSCREEN LIP BALM**

avobenzone, octinoxate, octocrylene stick

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75916-0664

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g

**Ingredient Name** 

# **Inactive Ingredients**

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)

YELLOW WAX (UNII: 2ZA36H0S2V)

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

JOJOBA OIL (UNII: 724GKU717M)	
LANOLIN (UNII: 7EV65EAW6H)	
.ALPHATO COPHERO L ACETATE, DL- (UNII: WR1WPI7EW8)	
VANILLA (UNII: Q74T35078H)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:75916-0664-8	1 in 1 BOX		
1	8.5 g in 1 TUBE, WITH APPLICATOR		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	0 1/19 /20 11			

# Labeler - Skin Alive, Ltd. (593384746)

Revised: 1/2011 Skin Alive, Ltd.