

SURFERS SKIN 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.

Surfers 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

Regains 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, Caprylic/Capric Triglyceride, Castor Oil, Jojoba Oil, Lanolin, Tocopheryl Acetate, Vanilla lip

Surfers 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.surfersskin.co

DIST. BY Quiver Dist, Bend Oregon, USA 97701

AS/ANZ STANDARD 2604-1998

Tested on Surfers - Not Animals

Net Wt. .3oz (8.5g)

SPF 30+

very water / sweat resistant

broad spectrum

UVA/UVB protection

Proven in extreme New Zealand conditions

Surfers Skin sunscreen lip balm

Net Wt. .30 oz (8.5g)

contains no nanoparticles - aminobenzoic acid (PABA)-free

surfersskin
sunscreen lip balm™

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



www.surfersskin.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, Caprylic/Capric Triglyceride, Castor Oil, Jojoba Oil, Lanolin, Tocopheryl Acetate, Vanilla lip.

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

EXPIRES :
LOT NUMBER :

spf30+

- very water / sweat resistant
- broad spectrum
- UVA / UVB protection



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

Drug Facts

Active Ingredients	Purpose
Avobenzene 2.5%	}...Sunscreen
Octinoxate 7.5%	
Octocrylene 5.0%	

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 develops and lasts. Keep out of reach of children.

Net Wt. .30 oz (8.5g)

CONTAINS NO NANOPARTICLES - AMINOBENZOIC ACID(PABA)- FREE

www.surfersskin.co

www.surfersskin.co

DIST. BY Quiver Dist.,Bend Oregon,USA 97701 AS/ANZ STANDARD 2604:1998

Tested on Surfers - Not Animals
NetWt. .30 oz (8.5g)

SURFERS SKIN SUNSCREEN LIP BALM

avobenzene, octinoxate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:759 16-0660
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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
AVOCADO OIL (UNII: 6VNO72PFC1)	

YELLOW WAX (UNII: 2ZA36H0S2V)

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

JOJOBA OIL (UNII: 724GKU717M)

LANOLIN (UNII: 7EV65EAW6H)

.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)

VANILLA (UNII: Q74T35078H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75916-0660-8	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	01/17/2011	

Labeler - Skin Alive, Ltd. (593384746)

Revised: 1/2011

Skin Alive, Ltd.