

SKIN STRONG - SKIN EQUIPMENT SPF 55 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick

True Balance Athletics LLC

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.

SKIN STRONG SKIN EQUIPMENT - SPF 55 SUNSCREEN STICK - DRUG FACTS LABEL

ACTIVE INGREDIENTS

AVOBENZONE 3.00%, HOMOSALATE 15.00%, OCTISALATE 5.00%, OCTOCRYLENE 10.00%, OXYBENZONE 6.00%

PURPOSE

SUNSCREEN

USES

- HELPS PREVENT SUNBURN
- HIGHER SPF GIVES MORE SUNBURN PROTECTION

WARNINGS:

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT:

- KEEP OUT OF THE EYES
- RINSE WITH WATER TO REMOVE

STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS OR LASTS

DIRECTIONS

- APPLY LIBERALLY 20 MINUTES BEFORE SUN EXPOSURE AND AS NEEDED
- FOR CHILDREN UNDER 6 MONTHS OF AGE, ASK A DOCTOR

SUN ALERT

Limiting sun exposure, wearing protective clothing and using sunscreen reduces the risk of skin aging, skin cancer and other harmful effects of the sun.

INACTIVE INGREDIENTS

BEESWAX, LAURYL LAURATE, OZOKERITE, CETEARYL BEHENATE, POLYBUTENE, CETYL ALCOHOL, STYRENE/ACRYLATES COPOLYMER, MYRISTYL MYRISTATE, TOCOPHEROL, COCOA SEED BUTTER, PHENOXYETHANOL, RETINYL PALMITATE, TETRAHEXYDECYL ASCORBATE

IMAGE OF LABEL

SPF55StickLabel.jpg

SPF 55

SKIN STRONG

SKIN EQUIPMENT



SPF 55 SUNSCREEN STICK

NET WT. 0.47 OZ (13.3 g)

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3.00%.....	Sunscreen
Homosalate 15.00%.....	Sunscreen
Octisalate 5.00%.....	Sunscreen
Octocrylene 10.00%.....	Sunscreen
Oxybenzone 6.00%.....	Sunscreen
Uses	
<ul style="list-style-type: none"> Helps prevent sunburn Higher SPF gives more sunburn protection 	
Warnings: For external use only	
When using this product:	
<ul style="list-style-type: none"> Keep out of eyes Rinse with water to remove 	
Stop use and ask a doctor if rash or irritation develops or lasts	
Directions:	
<ul style="list-style-type: none"> Apply liberally 20 minutes before sun exposure and as needed For children under 6 months of age, ask a doctor 	
Sun Alert- Limiting sun exposure, wearing protective clothing and using sunscreen reduces the risk of skin aging, skin cancer and other harmful effects of the sun.	
Inactive Ingredients: Beeswax, Lauryl Laurate, Ozokerite, Cetearyl Behenate, Polybutene, Cetyl Alcohol, Styrene/Acrylates Copolymer, Myristyl Myristate, Tocopherol, Cocoa Seed Butter, Phenoxyethanol, Retinyl Palmitate, Tetrahexyldecyl Ascorbate	

IRONMAN® and IRONMAN TRIATHLON® are registered trademarks of World Triathlon Corporation.

Distributed by:
True Balance Athletics, LLC.
P.O. Box 655
Bentonville, AR 72712
www.skinstrong.com



Pro Endorsed



SKIN STRONG - SKIN EQUIPMENT SPF 55 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51401-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
LAURYL LAURATE (UNII: GPW77G0937)	
CERESIN (UNII: Q1LS2UJO3A)	
CETEARYL BEHENATE (UNII: 7ARI9LTH0U)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCOA BUTTER (UNII: 512OYT1CRR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51401-002-01	13.3 g in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/30/2012	

Labeler - True Balance Athletics LLC (011072321)

Registrant - Dhaliwal Labs (016754201)

Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Labs		016754201	manufacture(51401-002)

Revised: 12/2012

True Balance Athletics LLC