

SKIN STRONG - SKIN EQUIPMENT SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

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 30 SUNSCREEN LOTION - DRUG FACTS LABEL

ACTIVE INGREDIENTS

AVOBENZONE 3.00%, HOMOSALATE 7.5%, OCTISALATE 5.00%, OCTOCRYLENE 2.75%, OXYBENZONE 4.00%

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 AGING, SKIN CANCER AND OTHER HARMFUL EFFECTS OF THE SUN.

INGREDIENTS

WATER, ADIPIC ACID/ DIETHYLENE DIGLYCOL GLYCERIN CROSSPOLYMER, C 12-15 ALKYL BENZOATE, ALOE BARBADENSIS LEAF EXTRACT, RETINYL PALMITATE, TOCOPHERYL ACETATE SODIUM ASCORBYL PHOSPHATE, STEARETH-21, TRIETHANOLAMINE, PROPYLENE GLYCOL, DECYL GLUCOSIDE, SORBITAN STEARATE, STEARETH-2, ACRYLATES/ C 10-30 ALKYL ACETATE CROSSPOLYMER, DIAZOLIDINYL UREA, METHYLPARABEN, CARBOMER, HYDROXYPROPYL, METHYLCELLULOSE, DISODIUM EDTA, PROPYLPARABEN

IMAGE OF LABEL

SPF30LotionLabel.jpg



Drug Facts	
Active Ingredients	Purpose
Avobenzone 3.00%.....	Sunscreen
Homosalate 7.50%.....	Sunscreen
Octisalate 5.00%.....	Sunscreen
Octocrylene 2.75%.....	Sunscreen
Oxybenzone 4.00%.....	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.	
Ingredients: Water, Adipic Acid/ Diethylene Diglycol Glycerin Crosspolymer, C12-15 Alkyl Benzoate, Aloe Barbadensis Leaf Extract, Retinyl Palmitate, Tocopheryl Acetate, Sodium Ascorbyl Phosphate, Steareth-21, Triethanolamine, Propylene Glycol, Decyl Glucoside, Sorbitan Stearate, Steareth-2, Acrylates/ C10-30 Alkyl Acetate Crosspolymer, Diazolidinyl Urea, Methylparaben, Carbomer, Hydroxypropyl Methylcellulose, Disodium EDTA, Propylparaben	
 	
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5140 1-030
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	27.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
STEARETH-21 (UNII: 53J3F32P58)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51401-030-01	118 mL in 1 BOTTLE, PUMP		

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(51401-030)

Revised: 12/2012

True Balance Athletics LLC