ACTIVE SPORT- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion Vi-Jon, Inc

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.

Active ingredients

Avobenzone 3%, Homosalate 11.7%, Octisalate 4.5%, Octocrylene 4.5%, Oxybenzone 5.4%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the rist of skin cancer and early skin aging caused by the sun

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 use and ask a doctor

if rash occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- 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 the sun, especially from 10 a.m. -2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: Ask a doctor

Other information

• protect the product from the excessive heat and direct sun

Inactive ingredients

water, propylene glycol, neopentyl glycol diheptanoate, styrene/acrylates copolymer, benzyl alcohol, tocopherol, triethanolamine, acrylates/C10-30 alkyl acrylate crosspolymer, oleth-3, polyamide-8, chlorphenesin, sodium ascorbyl phosphate, disodium EDTA

This product is not bein compared to Banana Boat SPORT with Powerstay Technology Sunscreen Lotion Broad Spectrum SPF 50+ for any other purposes nore is this product manufactured or distributed by Edgewell Personal Care, Distributor of Banana Boat.*

May stain or damage some fabrics or surfaces

Manufactured by: Vi-Jon, Inc., St. Louis, Mo 63114

Questions or Comments? 1-888-593-0593

www.mymountainfalls.com

793.000/793AA

Principal Display Panel

mountain falls

Compare to Banana Boat

paraben free

SPF 50

water resistant 80 minutes

non-greasy

active sport sunscreen lotion

BROAD SPECTRUM SPF 50

Made in the USA with US and foreign parts

8 FL OZ (236 mL)



ACTIVE SPORT

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0793	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.6 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	30.6 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	45.9 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	45.9 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	55.08 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
NEOPENTYL GLYCOL DIHEPTANO ATE (UNII: 5LKW3C543X)			
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
TOCOPHEROL (UNII: R0ZB2556P8)			
TROLAMINE (UNII: 9O3K93S3TK)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
OLETH-3 (UNII: BQZ26235UC)			
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)			
CHLORPHENESIN (UNII: 1670 DAL4SZ)			
SODIUM ASCORBYL PHOSPHATE (UNII: 836 SJG51DR)			
EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:0869-0793- 34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 12	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	12/0 1/20 12		

Labeler - Vi-Jon, Inc (790752542)

Registrant - Vi-Jon, Inc (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, Inc		790752542	manufacture(0869-0793)	

Revised: 5/2020 Vi-Jon, Inc