SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray Vi-Jon

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.

Sunscreen Lotion

752

Active ingredients

Avobenzone 3%

Homosalate 13%

Octisalate 5%

Octocrylene 7%

Oxybenzone 4%

Purpose

Sunscreen

Use

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk 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 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 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 excessive heat and direct sun

Inactive ingredients

water, sorbitol, triethanolamine, VP/eicosene copolymer, stearic acid, sorbitan isostearate, aluminum starch octenylsuccinate, benzyl alcohol, dimethicone, tocopherol, chlorphenesin, polyglyceryl-3 distearate, fragrance, carbomer, disodium EDTA

May stain or damage some fabrics or surfaces

*This product is not manufactured or distributed by Bayer, distributor of Coppertone Sunscreen Water Babies Broad Spectrum SPF 50

Made in the USA with US and foreign parts.

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

Questions or Comments? 1-888-593-0593

www.mymountainfalls.com

752.000/752AB

principal display panel

mountain falls

Compare to Coppertone

paraben free

water resistant 80 minutes

non-irritating

sunscreen for babies

BROAD SPECTRUM SPF 50

UVA/UVB

SUNSCREEN

8 FL OZ (236 mL)



SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0752
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	30.9 mg in 1 g	
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Ho mo sa late	133.9 mg in 1 g	
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	51.5 mg in 1 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	72.1 mg in 1 g	
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	41.2 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
TROLAMINE (UNII: 9O3K93S3TK)		
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)		
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ0 O 6 29 4)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
tocopherol (UNII: R0 ZB2556 P8)		
CHLORPHENESIN (UNII: 1670 DAL4SZ)		
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
EDETATE DISODIUM ANHYDROUS (UNII: 8 NLQ36 F6 MM)		

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:0869-0752- 34	236 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/07/2017	

Labeler - Vi-Jon (790752542)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0869-0752)

Revised: 5/2020 Vi-Jon