

**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 Spray
789**

Active ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 4%

Oxybenzone 5%

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

Flammable:

Do not use near heat, flame, or while smoking.

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
- avoid long term storage above 40°C (104°F)

Inactive ingredients

alcohol denat., acrylates/octylacrylamide copolymer, glycerin, tocopherol, fragrance, caprylic/capric triglyceride

May stain or damage some fabrics or surfaces

*This product is not manufactured or distributed by Bayer, distributor of Coppertone Sunscreen Continuous Spray Ultra Guard 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

789.000/789AA

principal display panel

Continuous Spray

mountain falls

Compare to Coppertone

paraben free

water resistant 80 minutes

SPF 50

sweat resistant

ultra sunscreen spray

BROAD SPECTRUM SPF 50

UVA/UVB sunscreen

NET WT 6 OZ (170 g)

Continuous
Spray


mountain
falls™

paraben
free

*Compare to
Coppertone®

SPF
50

water
resistant
80
minutes

sweat
resistant

ultra
sunscreen
spray

BROAD SPECTRUM
SPF 50

UVA/UVB sunscreen

NET WT 6 OZ (170 g)

SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0789
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzon (UNII: G63QQF2NOX) (AVOBENZON - UNII:G63QQF2NOX)	Avobenzon	26.07 mg in 1 g
Homosalat (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalat	86.9 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	43.45 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	34.76 mg in 1 g
OXYBENZON (UNII: 95OOS7VE0Y) (OXYBENZON - UNII:95OOS7VE0Y)	OXYBENZON	43.45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACRYLIC ACID/ISOPHORON DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	
glycerin (UNII: PDC6A3C0OX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0789-30	170 g in 1 BOTTLE, SPRAY; 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(0869-0789)