

## **SUNSCREEN- avobenzene, homosalate, octisalate, 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.*

-----

### **Sport Sunscreen Spray**

**730**

#### **Active ingredients**

Avobenzene 2%

Homosalate 15%

Octisalate 5%

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

#### **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, fragrance

May stain or damage some fabrics or surfaces

This product is not manufactured or distributed by Bayer, distributor of Coppertone Sport High Performance Sunscreen Continuous Spray UVA/UVB Broad Spectrum SPF 30.

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](http://www.mymountainfalls.com)

730.000/730AA

## principal display panel

Continuous Spray

mountain falls

Compare to Coppertone\*

paraben free

water resistant

80 minutes

SPF 30

sweat resistant

sport sunscreen spray

BROAD SPECTRUM

SPF 30

UVA/UVB

sunscreen

NET WT 2.5 FL OZ (71 g)



## SUNSCREEN

avobenzone, homosalate, octisalate, oxybenzone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0869-0730	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
Avobenzonone (UNII: G63QQF2NOX) (AVOBENZONONE - UNII:G63QQF2NOX)		Avobenzonone	20 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	
OXYBENZONONE (UNII: 95OOS7VE0Y) (OXYBENZONONE - UNII:95OOS7VE0Y)		OXYBENZONONE	40 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M)				
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)				
GLYCERIN (UNII: PDC6A3C0OX)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0869-0730-30	170 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
2	NDC:0869-0730-38	283 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
3	NDC:0869-0730-18	71 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
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(0869-0730)