

**SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray**  
**Family Dollar Services, 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.*

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**Ultra Sunscreen Spray**  
**790**

**Active ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2%

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, 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 30.

Distributed by: Family Dollar Services Inc.

10401 Monroe Rd., Matthews, NC 28105, USA

790.000/790AA

#### **Principal display panel**

Tropic Sun

Ultra Sunscreen Spray

Broad spectrum SPF 30

Compare to Coppertone Ultraguard Sunscreen\*

SPF 30

Water resistant (80 minutes)

UVA/UVB sunscreen

Paraben free

NET WT 6 OZ (170 g)



## SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-790
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	25.95 mg in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	86.5 mg in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	43.25 mg in 1 g

<b>Octocrylene</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		Octocrylene	17.3 mg in 1 g	
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)		OXYBENZONE	34.6 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)				
TOCOPHEROL (UNII: R0ZB2556P8)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-790-30	170 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part352	08/07/2017	

**Labeler** - Family Dollar Services, Inc. (024472631)

**Registrant** - Vi-Jon, Inc. (790752542)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi-Jon, Inc.		790752542	manufacture(55319-790)