

**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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**Sunscreen for Babies**  
**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

Distributed by Family dollar Services Inc.

10401 Monroe Rd.

Matthews, NC 28105, USA

752.000/752AB

#### **Principal Display Panel**

Tropic Sun

Sunscreen for Babies

Broad spectrum SPF 50

Compare to Coppertone Water Babies Sunscreen\*

SPF 50

Water resistant (80 minutes)

UVA/UVB sunscreen

Pediatrician tested

Paraben free

3 FL OZ (89 mL)



## SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-752
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	30.9 mg in 1 g
<b>Homosalate</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	133.9 mg in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	51.5 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	72.1 mg in 1 g

Oxybenzone (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	Oxybenzone	41.2 mg in 1 g
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### 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 OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
tocopherol (UNII: R0ZB2556P8)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-752-21	89 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2017	
2	NDC:55319-752-34	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** - Family Dollar Services, Inc (024472631)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc.		790752542	manufacture(55319-752)