

**KIDS SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone stick  
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.*

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**Drug Facts**

**claims**

SOLAR SCREEN

KIDS SUNSCREEN STICK SPF 55

Broad Spectrum SPF 55

**Active ingredients**

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

Oxybenzone 6%

**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 section 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 a 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**

beeswax, lauryl laurate, polybutene, cetyl alcohol, ozokerite, cetearyl behenate, myristyl myristate, styrene/acrylates copolymer, tocopherol, Theobroma cacao (cocoa) seed butter, retinyl palmitate, phenoxyethanol, tetrahexyldecyl ascorbate

**disclaimer**

May stain or damage some fabrics or surfaces

this product is not manufactured or distributed by Bayer distributor of Coppertone Kids Sunscreen Stick Broad Spectrum SPF 55

**Disclaimer**

Distributed by: Vi-Jon, Inc.  
8515 Page Ave.  
St. Louis, MO 63114  
791.000/791AA

**principal display panel**

SPF 55

SOLAR SCREEN

KIDS

SUNSCREEN

STICK SPF 55

Broad Spectrum

SPF 55

Water Resistant

(80 minutes)

Pediatrician Tested

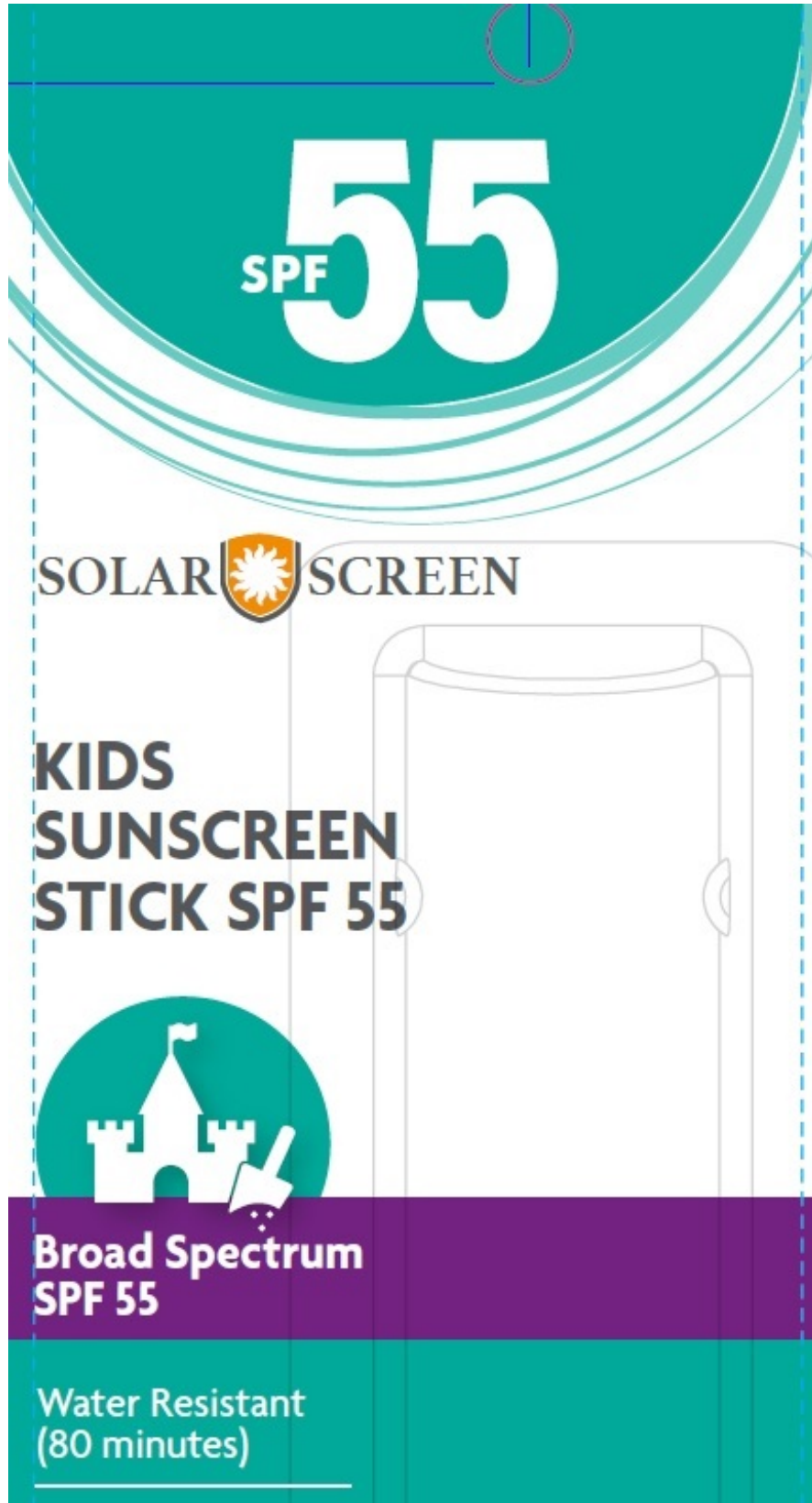
PABA Free

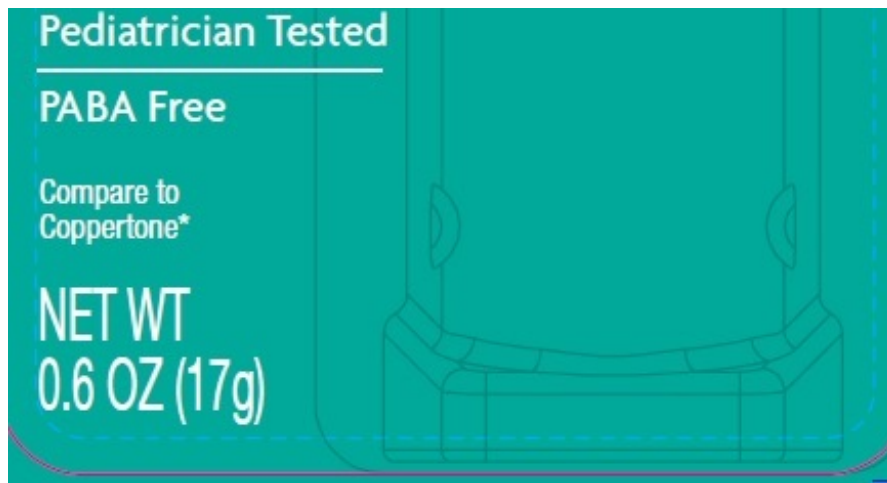
Compare to

Coppertone

NET WT

0.6 OZ (17g)





## KIDS SUNSCREEN

avobenzene, homosalate, octisalate, octocrylene, oxybenzone stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11344-791
<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 mg in 1 g
<b>homosalate</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	homosalate	150 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
<b>octocrylene</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	octocrylene	100 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	60 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>LAURYL LAURATE</b> (UNII: GPW77G0937)	
<b>POLYBUTENE (1400 MW)</b> (UNII: 1NA5AO9GH7)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>CETEARYL BEHENATE</b> (UNII: 7ARI9LTH0U)	
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-791-84	1 in 1 BLISTER PACK	07/01/2017	
1		17 g in 1 APPLICATOR; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/01/2017	

**Labeler** - Vi-Jon (150931459)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(11344-791)

Revised: 8/2017

Vi-Jon