

SUNSCREEN- avobenzone, homosalate, octisalate, 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.

Sunscreen Spray for Kids
727

Active ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

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

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, Aloe barbadensis leaf extract, fragrance, Cocos nucifera (coconut) oil, mineral oil

May stain or damage some fabrics or surfaces

*This product is not manufactured or distributed by Bayer, distributor of Coppertone Kids Sunscreen Continuous Spray Broad Spectrum SPF 50.

Distributed by: Family Dollar Services Inc., 10401 Monroe Rd., Matthews, NC 28105, USA

principal display panel

Tropic Sun

Sunscreen spray for kids

Broad spectrum SPF 50

Compare to Coppertone Kids Sunscreen

SPF 50

Water resistant (80 minutes)

UVA/UVB Sunscreen

Pediatrician tested

Paraben free

NET WT 6 OZ (170 g)



SUNSCREEN

avobenzone, homosalate, octisalate, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-727
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	26.49 mg in 1 g
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	132.45 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	44.15 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	52.98 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCONUT OIL (UNII: Q9L0O73W7L)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-727-30	170 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
2	NDC:55319-727-38	283 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/07/2017	
3	NDC:55319-727-18	71 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 - Family Dollar Services, Inc (024472631)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55319-727)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55319-727)