

**KIDS SPF 50- avobenzene 3% homosalate 10% octisalate 5% octocrylene 4% oxybenzone 5% spray
TopCare**

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.

Drug Facts

Active ingredients	Purpose
Avobenzene 3%.....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 4%.....	Sunscreen
Oxybenzone 5%.....	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection
• retains SPF after 80 minutes of activity in the water or sweating • provides moderate protection against sunburn

Warnings

Flammable: Do not use near heat, flame, or while smoking.

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 or irritation develops and last

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

Directions • Apply liberally 15 minutes before sun exposure and as needed.
• Children under 6 months of age: ask a doctor. • 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. • Hold container 4 to 6 inches from the skin to apply. • Do not spray directly into face. Spray on hands then apply to face. • Do not apply in windy conditions. • Use in a well-ventilated area. • For sunscreen use: • apply to all skin exposed to the sun. • Reapply as needed or after towel drying, swimming, or sweating.

Other information • protect the product in this container from excessive heat and direct sun • may stain fabrics.

Inactive ingredients Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Retinyl Palmitate, Stearoxtrimethylsilane, Tocopherol.

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 4%	Sunscreen
Oxybenzone 5%	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection
 • 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 eyes with water to remove. • Keep away from face to avoid breathing it • Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
 • spray liberally and spread evenly by hand 15 minutes before sun exposure
 • reapply: • after 80 minutes of swimming or sweating
 • immediately after towel drying • at least every 2 hours
 • hold container 4 to 6 inches from the skin to apply
 • do not spray directly into face. Spray on hands then apply to face.
 • do not apply in windy conditions
 • use in a well-ventilated area
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 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-sleeve shirts, pants, hats, and sunglasses
 • children under 6 months: Ask a doctor

Other information • protect this product from excessive heat and direct sun. • may stain fabrics.

Inactive ingredients Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Retinyl Palmitate, Stearoxtrimethylsilane, Tocopherol.


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 This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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Water Resistant
(80 minutes)
UVA/UVB Protection


TopCare®
kids



BROAD SPECTRUM
SPF 50

KIDS
Sunscreen Spray

NET WT 6 OZ (170 g)



KIDS SPF 50

avobenzone 3% homosalate 10% octisalate 5% octocrylene 4% oxybenzone 5% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzon e (UNII: G63QQF2NOX) (AVOBENZON - UNII:G63QQF2NOX)	Avobenzon	3 g in 100 g
Homosalat e (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalat	10 g in 100 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 g
Octocrylen e (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylen	4 g in 100 g
Oxybenzon e (UNII: 95OOS7VE0Y) (OXYBENZON - UNII:95OOS7VE0Y)	Oxybenzon	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Diethylhexyl Syringylidenemalonate (UNII: 3V5U97P248)	
Glycerin (UNII: PDC6A3C0OX)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
Tocopherol (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-723-05	170 g in 1 CAN; Type 0: Not a Combination Product	02/15/2016	
2	NDC:36800-723-06	227 g in 1 CAN; Type 0: Not a Combination Product	02/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/15/2016	

Labeler - TopCare (006935977)**Registrant** - Product Quest (927768135)**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest		927768135	manufacture(36800-723) , label(36800-723)