LEADER KIDS SPF 50 SUNSCREEN- homosalate, octisalate, oxybenzone, octocrylene, avobenzone aerosol, spray Cardinal Health

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.

Leader Kids SPF 50 Continuous Spray Sunscreen

Active Ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 4.0%, Oxybenzone 5.0%

Purpose

Sunscreen

Uses

• 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
- avoid long term storage above 104 deg F (40 degC)

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120 deg 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

- Apply liberally 15 minutes before sun exposure
- Hold can 4-6 inches away form body, spray evenly to ensure complete coverage
- Do not spray into face. Spray into hand and apply to face.
- Use in well ventilated, but not windy areas
- Reapply:
- After 80 minutes of swimming or sweating
- Immdiately after towel drying
- At least every 2 hours
- Spending time in the sun increases your risk of skin cancer and early skin aging. To
 decrease their 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 am 2 pm
- wear long sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients

Alcohol denat. (73.2% V/V), acrylates/octylacrylamide copolymer, stearoxytrimethylsilane, glycerin, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), fragrance, retinyl palmitate (vitamin A palmitate), caprylic/capric triglyceride



Kids Sunscreen

Clear Continuous Spray

BROAD SPECTRUM SPF 50



Sprays at Any Angle Water Resistant (80 Minutes)



6 FL OZ (177mL)

Drug Facts

Active ingredients

Avobenzone 3.0% + Homosalate 10.0% Octocrytene 4.0% Oxybenzone 5.0%

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Do not use on damaged or broken skin.

When using this product • keep out of eyes. Rinse with water to remove. • 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

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 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:
 Imit 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

Imactive ingradients
alcohol denat. (73.2% V/l), acrylates/octylacrylamide copolymer, stearusytrimethylsilane,
dyberni, diethylsevyl syringylidenemalonate, tocopherol (vitamin E), fragrance, retinyl
palmitate (vitamin A palmitate), caprylis/capric trighyceride

protect this product from excessive heat and direct sun
 may stain or damage some fabrics, materials or surfaces

Questions or comments? Call toll free 1-800-200-6313

"This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc. distributor of Coppertone® brand products,

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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www.myleader.com





LEADER KIDS SPF 50 SUNSCREEN

homosalate, octisalate, oxybenzone, octocrylene, avobenzone aerosol, spray

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:37205-723

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S) | HOMOSALATE | 100 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 40 mg in 1 mL |
| OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y) | OXYBENZONE | 50 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZ ONE | 30 mg in 1 mL |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | |
| STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248) | | | | |
| TOCOPHEROL (UNII: R0ZB2556P8) | | | | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | | | | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | | | | |
| ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK) | | | | |

| l | P | Packaging | | | | |
|---|---|----------------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | NDC:37205-723- 30 | 177 mL in 1 CAN; Type 0: Not a Combination Product | 01/15/2012 | | |

| Marketing In | Marketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 01/15/2012 | | |
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Labeler - Cardinal Health (097537435)

Revised: 1/2022 Cardinal Health