CARDINAL HEALTH LEADER SPF 50 KIDS SUNSCREEN CLEAR CONTINUOUSavobenzone, homosalate, octisalate, octocrylene, oxybenzone aerosol, spray Cardinal Health, 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.

Cardinal Health Leader SPF 50 Kids Sunscreen Clear Continuous Spray

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°F (40°C)

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. • keep away from face to avoid breathing it. • do not store at temperatures above 120° F.

Stop use and ask doctor if

rash occurs.

Keep out of reach of children.

If 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
- hold can 4-6 inches away from skin to apply
- do not spray directly into face. Spray into hand and then apply to face.
- do not apply in windy conditions
- use in well-ventilated area
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: Ask a doctor
- **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-sleeved shirts, pants, hats, and sunglasses

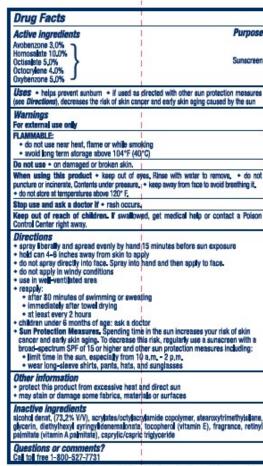
Other Information

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

Inactive ingredients

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





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CIN 5394242 REV. 11/17

CARDINAL HEALTH LEADER SPF 50 KIDS SUNSCREEN CLEAR CONTINUOUS

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

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0325 Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | |
|--|--------------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZ ONE | 30 mg in 1 g | |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 100 mg in 1 g | |

| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 g |
|--|-------------|--------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 40 mg in 1 g |
| OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y) | OXYBENZ ONE | 50 mg in 1 g |

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

| Packaging | | | | |
|----------------------|---|-------------------------|-----------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| NDC:70000- 0325-1 | 156 g in 1 CAN; Type 0: Not a Combination Product | 02/20/2018 | | |

| Marketing Information | | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 02/20/2018 | | |
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Labeler - Cardinal Health, Inc. (063997360)

Revised: 1/2022 Cardinal Health, Inc.