

SUNSCREEN SPF50- avobenzene , homosalate , octisalate , oxybenzone , octocrylene lotion SKIN KIDZ CC

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.

Sun Skin SPF50 Sunscreen

PURPOSE

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures
 - decreases the risk of skin cancer and early skin aging caused by the sun

Active ingredients

Avobenzene 3%, Homosalate 11.7%,
Octisalate 4.5%, Oxybenzone 5.4%,
Octocrylene 4.5%

Directions

- apply generously 15 minutes before sun exposure
- ensure complete coverage to the are above the lip, nose, and tops of ears
- reapply: - after 80 minutes of swimming or sweating – immediately after towel drying – at least every 2 hours.

WARNING AND Pracaution

- 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.
- If rash occurs, stop use and ask a doctor

ASK DOCTOR SECTION

- If rash occurs, stop use and ask a doctor

KEEP OUT OF REACH OF CHILDREN SECTION

- KEEP OUT OF REACH OF CHILDREN SECTION
- If swallowed, get medical help or contact a Poison Control Center right away.

INACTIVE INGREDIENT

ingredients: water, propylene glycol,
polyurethane-34, cetyl alcohol, potassium cetyl

phosphate, glycerin, sorbitan mono stearate,
polysorbate 60, phenoxyethanol,
ethylhexylglycerin, potassium hydroxide,
dimethicone, tocopheryl acetate, acrylates/C10-
30 alkyl acrylate crosspolymer, arginine, sodium
ascorbyl phosphate, disodium EDTA

Product Label



SUNSKIN
Sunscreen

SPF50

UVA UVB

**Broad Spectrum
Pollution Shield**

Non-Whitening
Non-Greasy

with Antioxidants
Vitamin C & E

NET WT 1.8 OZ (51g)

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------|
| Drug Facts | Active ingredients | Purpose |
| Avobenzene 3%, Homosalate 11.7%, Octisalate 4.5%, Oxybenzone 5.4%, Octocrylene 4.5% | } | 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 ●Do not use on damaged or broken skin ●When using this product keep out of eyes. Rinse with water to remove. ●If rash occurs, stop use and ask a doctor ●Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | | |
| Directions ●apply generously 15 minutes before sun exposure ●ensure complete coverage to the area above the lip, nose, and tops of ears ●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 this product from excessive heat and direct sun ●may stain some fabrics ●package contains small parts, which could cause a choking hazard | | |
| Inactive ingredients: water, propylene glycol, polyurethane-34, cetyl alcohol, potassium cetyl phosphate, glycerin, sorbitan mono stearate, polysorbate 60, phenoxyethanol, ethylhexylglycerin, potassium hydroxide, dimethicone, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, arginine, sodium ascorbyl phosphate, disodium EDTA | | |
| Questions? Visit www.zentraedionline.com or Phone: 302-250-4447 or +27 100 600 999 or e-mail: info@zentraedionline.com | | |
| Skin Kidz cc: 28 6th Avenue, Melville Johannesburg Made in South Africa | | |

SUNSCREEN SPF50

avobenzene , homosalate , octisalate , oxybenzone , octocrylene lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72376-001 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------|-------------------|---------------|
| Avobenzene (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | Avobenzene | 30 mg in 1 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 117 mg in 1 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 45 mg in 1 g |

| | | |
|-----------------------------------------------------------------------|-------------|--------------|
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE | 54 mg in 1 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 45 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------------------------------------------------------------|----------|
| Propylene glycol (UNII: 6DC9Q167V3) | |
| Water (UNII: 059QF0K00R) | |
| POLYURETHANE-34 (40 MPA, TENSILE STRENGTH OF FILM AT BREAK) (UNII: 77KA306NNF) | |
| Cetyl alcohol (UNII: 936JST6JCN) | |
| Potassium cetyl phosphate (UNII: 03KCY6P7UT) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Sorbitan monostearate (UNII: NVZ4I0H58X) | |
| Polysorbate 60 (UNII: CAL22UVI4M) | |
| Phenoxyethanol (UNII: HIE492ZZ3T) | |
| Ethylhexylglycerin (UNII: 147D247K3P) | |
| Potassium hydroxide (UNII: WZHBC48M4T) | |
| Dimethicone (UNII: 92RU3N3Y1O) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) | |
| Arginine (UNII: 94ZLA3W45F) | |
| Sodium ascorbyl phosphate (UNII: 836SJK51DR) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:72376-001-01 | 51 g in 1 BOTTLE; Type 0: Not a Combination Product | 06/11/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part352 | 06/11/2018 | |

Labeler - SKIN KIDZ CC (538908603)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| SKIN KIDZ CC | | 538908603 | manufacture(72376-001) |

Revised: 6/2018

SKIN KIDZ CC