

SUNZONE KIDS SPF 45 BROAD SPECTRUM- octocrylene, octisalate, homosalate, avobenzone and oxybenzone aerosol, spray
Empack Spraytech 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.

Active Ingredients

Avobenzone....2.0%

Homosalate.....10%

Octisalate.....5.0%

Octocrylene.....2.0%

Oxybenzone....5.0%

Purpose

Sunscreen

Uses

Helps prevent sunburn

if used as directed with other sun protection measures (see direction), decrease the risk of skin cancer and early skin aging 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 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

Inactive Ingredients

Acrylates Copolymer, Alcohol Denat., Aloe Barbadensis Leaf Extract, Bisabolol,

Bis-Hydroxyethoxypropyl Dimethicone, Camellia Oleifera (Japanese Green Tea) Leaf Extract,

Ethylhexylglycerin, Diethylhexyl 2,6-Naphthalate, Fragrance, Phenoxyethanol, Tocopherol Acetate (Vitamin E)

Other Information

Protect this product from excessive heat and direct sun

May stain some fabrics or surfaces

Questions or Comments

call toll free 1-866-923-2665

Empack Spraytech Inc.

98 Walker Drive, Brampton, Ontario

L6T 4H6

www.sunzone.ca

Made in Canada

Please Recycle

CLEAR CONTINUOUS SPRAY



SUNSCREEN



**WATER RESISTANT
(80 MINUTES)**

Light • Non-greasy
• With Aloe, Vitamin E,
& Green Tea Antioxidants

6 fl oz (177 mL)

- Provides broad-spectrum UVA/UVB protection
- Ultra light sheer mist, and a non-greasy finish
- Applies easily to hard to reach areas • Oil-free • PABA free • Paraben Free

Drug Facts

Active Ingredients

Avobenzone 2.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 2.0%, 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
- Do not use on damaged or broken skin
- When using this product 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 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

Inactive Ingredients

Acrylates Copolymer, Alcohol Denat., Aloe Barbadensis Leaf Extract, Bisabolol, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Diethylhexyl 2,6-Naphthalate, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Tocopheryl acetate (Vitamin E)

Other Information

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or Comments?

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Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50021-151 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 3.0 g in 150 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 7.5 g in 150 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 15.0 g in 150 g |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3.0 g in 150 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 7.5 g in 150 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| BIS-HYDROXYETHOXYPROPYL DIMETHICONE (50 CST) (UNII: YP714N2H05) | |
| DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60) | |
| .BETA.-BISABOLOL (UNII: LP618AV2EA) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:50021-151-01 | 150 g in 1 CAN | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 11/19/2012 | |

Labeler - Empack Spraytech Inc (252047519)**Registrant** - Empack Spraytech Inc (252047519)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Empack Spraytech Inc | | 252047519 | manufacture(50021-151) |