

SUNZONE KIDS SPF 60 BROAD SPECTRUM- octinoxate, octocrylene, octisalate, oxybenzone, avobenzone and homosalate. 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.

DRUG FACTS FOR SUNZONE KIDS SPF 60

Active Ingredients

Octinoxate5.0%
Octocrylene..... 5.0%
Octisalate.....5.0%
Oxybenzone..... 6.0%
Avobenzone.....3.0%
Homosalate.....12.0%

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

- 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 hand then apply to face
- Do not apply in windy conditions

- Use in a well-ventilated area
- Sun protection measures. Spending time in the sun increase the 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

Spray liberally and spread evenly by hand 15 minutes before sun exposure.

Other Information

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

Inactive Ingredients

Acrylates Copolymer, Alcohol Denat., Aloe Barbadensis Leaf Extract, Bisabolol, Bis-Hydroxyethoxypropyl Dimethicone, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Ethylhexylglycerin, Ethylhexyl Methoxycrylene, Fragrance, Phenoxyethanol, Tocopherol Acetate (Vitamin E)

CLEAR CONTINUOUS SPRAY



SUNSCREEN



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 | Purpose |
|--|-----------|
| Avobenzone 3.0%, Homosalate 12.0%, Octinoxate 5.0%, Octisalate 5.0%, Octocrylene 5.0%, Oxybenzone 6.0% | 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

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- 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, Bis-Hydroxyethoxypropyl Dimethicone, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Diethylhexyl 2,6-Naphthalate, Ethylhexylglycerin, Fragrance, 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?

Call toll free 1-866-923-2665



Empack Spraytech Inc.

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L6T 4H6 CANADA

www.sunzone.ca
Made in Canada



Please recycle

SUNZONE KIDS SPF 60 BROAD SPECTRUM

octinoxate, octocrylene, octisalate, oxybenzone, avobenzone and homosalate. aerosol, spray

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50021-061 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.75 g in 155 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7.75 g in 155 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 7.75 g in 155 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 9.30 g in 155 g |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 4.65 g in 155 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 18.60 g in 155 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |
| CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| BIS-HYDROXYETHOXYPROPYL DIMETHICONE (50 CST) (UNII: YP714N2H05) | |
| DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:50021-061-01 | 155 g in 1 CAN | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 11/16/2012 | |

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

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Empack Spraytech Inc | | 252047519 | manufacture(50021-061) |