

SUNZONE FAMILY SUNSCREEN SPF-60 BROAD SPECTRUM- avobenzone and octinoxate lotion

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 Family Sunscreen SPF 60

Active Ingredients

Avobenzone.....3%

Octinoxate.....4%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only

When using the product do not get into eyes. If contact occurs, rinse thoroughly with water

Stop use and ask a doctor if irritation 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 and spread evenly 15 minutes before sun exposure
- Reapply after 80 minutes of swimming or sweating
- immediately after swimming, towel drying
- At least every 2 hours

SUN PROTECTION MEASURES. Spending time in the sun increases your risk of skin cancer and early skin damage. To decrease this risk, regularly use a sunscreen with broad spectrum SPF 15 or higher and other sun protection measures including;

- Limit time in the sun, especially from 10 a.m-2p.m
- Wear long-sleeve shirts, pants, hats and sunglasses

Children under 6 months: **ASK A DOCTOR**

Inactive Ingredients

Acrylates Copolymer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Ammonium Acryloyldimethyltaurate/VP Copolymer, C12-15 Alkyl Benzoate, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Carthamus Tinctorius (safflower) Oleosomes, dl-alpha Tocopheryl acetate, Ethylhexylglycerin, fragrance, glycerin, Octyldodecyl Citrate Crosspolymer, Phenoxyethanol, Phenyl Trimethicone, Water

Information

Protect this product from excessive heat and direct sun

May stain some fabrics or surfaces

Question 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 3.0%, Homosalate 12.0%, Octinoxate 5.0%,
Octisalate 5.0%, Octocrylene 5.0%, Oxybenzone 6.0%

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, 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?

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L6T 4H6 CANADA

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SUNZONE FAMILY SUNSCREEN SPF-60 BROAD SPECTRUM

avobenzone and octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50021-243
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	9.36 g in 234 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	7.02 g in 234 g

Inactive Ingredients

Ingredient Name	Strength
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
TRIOCTYLDODECYL CITRATE (UNII: 35X8CT063R)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE49ZZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50021-243-01	234 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/13/2012	

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

Name	Address	ID/FEI	Business Operations
Empack Spraytech Inc.		252047519	manufacture(50021-243)

Revised: 11/2012

Empack Spraytech Inc.