

**SUNZONE FAMILY SUNSCREEN SPF 30 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 FAMILY SPF 30

Active Ingredients

Octinoxate 7.5%

Octocrylene 7.5%

Octisalate 5.0%

Oxybenzone 4.0%

Avobenzone 3.0%

Homosalate 2.4%

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

sun
zone

SUNSCREEN



- 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%, Homosalate 2.4%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 7.5%, Oxybenzone 4.0%.	Purpose Sunscreen
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Uses

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Warnings

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- 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.
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- 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

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

Other Information

- Protect this product from excessive heat and direct sun
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Questions or Comments?
Call toll free 1-866-923-2665



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L6T 4H6 CANADA
www.sunzone.ca
Made in Canada



SUNZONE FAMILY SUNSCREEN SPF 30 BROAD SPECTRUM

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50021-144
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	11.48 g in 153 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	11.48 g in 153 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	7.65 g in 153 g
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	6.12 g in 153 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4.59 g in 153 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.40 g in 153 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:50021-144-01	153 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/08/2012	

Labeler - Empack Spraytech Inc. (252047519)

Registrant - Empack Spraytech Inc. (252047519)

Establishment

Name	Address	ID/FEI	Business Operations
Empack Spraytech Inc		252047519	manufacture(50021-144)

Revised: 11/2012

Empack Spraytech Inc.