

SUNZONE KIDS SPF 30 SUNSCREEN BROAD SPECTRUM- octinoxate and avobenzone 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 Kids SPF 30 Sunscreen

Active Ingredients

Octinoxate 2.0%

Avobenzone 0.75%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only

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

Stop Use and ask a doctor if irritation or rash 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 towel drying
- at least every 2 hours
- 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 am - 2 pm
- Wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 Months: ASK A DOCTOR

Inactive Ingredients

Acrylates Copolymer, Aloe Barbadosensis Leaf Extract, Aminomethyl Propanol, Ammonium Acryoldimethyltaurate/VP Copolymer, C12-15 Alkyl Benzonate, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Carthamus Tinctorius (Safflower) Oleosomes, Ethylhexylglycerin, Fragrance, Glycerin, Phenoxyethanol, Phenyl Trimethicone, Tocopheryl acetate (Vitamin E), Water

Protect this product from excessive heat and direct sun

May stain some fabrics or surfaces

Call toll free 1-866-923-2665

Empack Spraytech Inc.

98 Walker drive, Brampton, Ontario

L6T 4H6

www.sunzone.ca

Made in Canada

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**sun
zone**
**SUNSCREEN
LOTION**



Patented
OLEOSOME TECHNOLOGY
derived from
PLANT SEEDS

8 fl oz (237mL)

30 SPF

SunZone Sunscreen Lotion provides high sunburn protection against broad spectrum UVA/UVB rays. This non-greasy, lightweight sunscreen is absorbed quickly, leaving skin soft, smooth and oil-free. Unique formula allows for a dramatic increase in sun protection – with the highest level of safety – by replacing harmful chemicals with ingredients that are naturally derived from plant seeds.

- PABA Free • Paraben Free

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Information

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Questions or Comments?

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octinoxate and avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50021-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.70 g in 235 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.76 g in 235 g

Inactive Ingredients

Ingredient Name	Strength
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50021-300-01	235 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/12/2012	

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

Name	Address	ID/FEI	Business Operations
Empack Spraytech Inc		252047519	manufacture(50021-300)