

**SUNZONE BABY 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.*

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**Drug Facts for SunZone Baby 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](http://www.sunzone.ca)

Made in Canada

Please Recycle

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



Patented  
**OLEOSOME TECHNOLOGY**  
derived from  
**PLANT SEEDS**

8 fl oz (237mL)

**60 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

**Drug Facts**

Active Ingredients	Purpose
Avobenzone 3.0%, Octinoxate 4.0%	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 a.m.- 2 p.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, Ethylhexylglycerin, Fragrance, Glycerin, Octyldodecyl Citrate Crosspolymer, Phenoxyethanol, Phenyl Trimethicone, Tocopheryl acetate (Vitamin E), Water

**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 Dr., Brampton, ON  
L6T 4H6 CANADA

[www.sunzone.ca](http://www.sunzone.ca)

Made in Canada



Please recycle

**SUNZONE BABY SUNSCREEN SPF-60 BROAD SPECTRUM**

avobenzone and octinoxate lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50021-241
<b>Route of Administration</b>	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: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50021-241-01	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(50021-241)