

SUNZONE BABY SUNSCREEN SPF-60 BROAD SPECTRUM- avobenzone and octinoxate lotion
Empack Spraytech Inc.

50021-241 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

Made in Canada

Please Recycle

Directions

Apply liberally and spread evenly 15 minutes before sun exposure

Reapply after 80 minutes to 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, expectiron sfrom 10 a.m. to 2 p.m. Wear long sleeve shirts, pants, hats and sunglasses

Children under 6 months: Ask a doctor

Warning

For external use only

**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?

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SUNZONE BABY SUNSCREEN SPF-60 BROAD SPECTRUM

avobenzone and octinoxate lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50021-241

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: 5077ELOC60)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/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; Type 0: Not a Combination Product	11/13/2012	12/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/13/2012	12/31/2022

Labeler - Empack Spraytech Inc. (252047519)

Registrant - Empack Spraytech Inc. (252047519)

Establishment

Name	Address	ID/FEI	Business Operations
Empack Spraytech Inc.		252047519	manufacture(50021-241)