

SAFE SEA SUNSCREEN WITH JELLYFISH STING PROTECTIVE SPF 15 - octinoxate, zinc oxide lotion

Nidaria Technology Ltd.

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.

Safe Sea Sunscreen With Jellyfish Sting Protective SPF 15

Active Ingredients

Active Ingredients	Purpose
Octinoxate 7.5 %, Zinc Oxide 2 %.....	Sunscreen

Uses

- Helps prevent sunburn. - Sun Protection Factor 15. - Retains SPF after 80 minutes of activity in the water or perspiring.

Warning

- For external use only.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if skin irritation or rash develops.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center Immediately.

Directions

- Adults and children six months of age and older. Apply Liberally to all exposed areas 10 minutes before sun or water exposure. - Ensure complete coverage. - Reapply after prolonged swimming and towel drying.

Other Information

- Give particular attention to coverage of arms and legs. - In water infested by Sea Lice, Safe Sea should also be applied under the bathing suit. Jellyfish can be dangerous. This product should not be considered a recommendation to go into jellyfish infested water, nor is it a guarantee against stings. - In case of sting do not use Safe Sea as a treatment - seek medical attention. * Tested against Sea nettle (Chrysaora), Atlantic Box jellyfish (Chiropsalmus) and Rhopilema. Date on file.

Inactive ingredients

Deionized Water, Cyclomethicone, Mineral Oil, Lauryl PEG/PPG-18/18 Methicon, Cetyl dimethicone, Stearyl Dimethicone, Ceresine, Hydrogenated Castor Oil, Plankton extract, Propylene Glycol, Diazolidinyl Urea, Propylparaben, Methylparaben, Lanthanum Chloride, Magnesium Chloride, Sodium Citrate, Tetrasodium EDTA, Trimethoxycaprylylsilane, Glycoproteins, Glycosaminoglycans, Fragrance, Calcium Chloride.

Purpose

Sunscreen

Description

SAFE SEA Sunscreen SPF 15 With Jellyfish Sting Protective Lotion The world's only sunscreen lotion scientifically developed to help prevent the stings from most jellyfish*, Sea nettle, Sea lice (Seabathers eruption). Dermatologist tested. UVAandUVB protection For sensitive skin. Water resistant. Distributed by Nidaria Technology ltd. 420 Lexington Avenue Suite 2400 New York, New York 10170 Made in Israel. www.nidaria.com US Patents No. 6338837 / 6406709 / 6132747 NDC - 0654350115 7 13026 10115 5

SAFE SEA Sunscreen SPF 15 With Jellyfish Sting Protective Lotion

SAFE SEA Sunscreen with JELLYFISH STING PROTECTIVE LOTION SPF 15 Helps Prevent Stings from Jellyfish and Sea Lice UVA, UVB, Water Resistant Clinically Tested 4 fl. oz. (118 ml)

Product Package Outer Label A

SAFESEA[®]

Sunscreen SPF 15 With Jellyfish Sting Protective Lotion

The world's only sunscreen lotion scientifically developed to help prevent the stings from most jellyfish, Sea nettle, Sea lice (Seabathers eruption). Dermatologist tested. UVA&UVB protection For sensitive skin. Water resistant.*

Drug Facts	
Active Ingredients	Purpose
Octinoxate 7.5%, Zinc Oxide 2%.....	Sunscreen

Uses • Helps prevent sunburn. • Sun Protection Factor 15. • Retains SPF after 80 minutes of activity in the water or perspiring.

Warning • For external use only. • When using this product, keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if skin irritation or rash develops. • Keep out of reach of children. If swallowed, get medical help or contact a

Poison Control Center Immediately.

Directions • Adults and children six months of age and older. Apply Liberally to all exposed areas 10 minutes before sun or water exposure. • Ensure complete coverage. • Reapply after prolonged swimming and towel drying.

Other Information • Give particular attention to coverage of arms and legs. • In water infested by Sea Lice, Safe Sea[®] should also be applied under the bathing suit. • **Jellyfish can be dangerous.** This product should not be considered a recommendation to go into jellyfish infested water, nor is it a guarantee against stings. • In case of sting do not use Safe Sea[®] as a treatment – seek medical attention.
* Tested against Sea nettle (Chrysaora), Atlantic Box jellyfish (Chiropsalmus) & Rhopilema. Data on file.

Inactive ingredients Deionized Water, Cyclomethicone, Mineral Oil, Lauryl PEG/PPG-18/18 Methicon, Cetyl dimethicone, Stearyl Dimethicone, Ceresine, Hydrogenated Castor Oil, Plankton extract, Propylene Glycol, Diazolidinyl Urea, Propylparaben, Methylparaben, Lanthanum Chloride, Magnesium Chloride, Sodium Citrate, Tetrasodium EDTA, Triethoxycaprylylsilane, Glycoproteins, Glycosaminoglycans, Fragrance, Calcium Chloride.

Distributed by
Nidaria Technology Ltd.
420 Lexington Avenue Suite 2400
New York, New York 10170

Made in Israel. www.nidaria.com
US Patents No. 6338837 /
6406709 / 6132747



Product Package Outer Label B



SAFE SEA

**Sunscreen
with
JELLYFISH STING
PROTECTIVE
LOTION**



*Helps Prevent Stings from
Jellyfish & Sea Lice*

**UVA, UVB, Water Resistant
Clinically Tested**

4 fl. oz. (118 ml)

SAFE SEA SUNSCREEN WITH JELLYFISH STING PROTECTIVE SPF 15

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65435-0116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM DICHOROACETATE (UNII: 42932X67B5)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65435-0116-5	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2011	

Labeler - Nidaria Technology Ltd. (514977487)

Establishment

Name	Address	ID/FEI	Business Operations
Cellango Crystalline Ltd.		532199064	manufacture

Revised: 11/2011

Nidaria Technology Ltd.