

SAFE SEA SPF 30- zinc oxide lotion
Nidaria Technology Ltd.

Drug Facts

Active ingredient

Zinc Oxide 10.9%

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 aging skin caused by the sun

Warnings

- **For external use only**
- **Do not use on damaged** or broken skin
- **When using this product** keep out of eyes. Rinse with water to remove
- **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.

Directions

- Apply liberally 15 minutes before sun exposure
- reapply: After 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- 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 a broad spectrum SPF of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. to 2 p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor.

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.

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Benzoic Acid, Benzyl Alcohol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Calcium Chloride, Caprylic / Capric triglyceride, Chlorphenisine, Dehydroacetic Acid, Dibutyl Adipate, Hydrogenated Castor Oil, Lanthanum Chloride, Magnesium Chloride, Magnesium Stearate, Panthenol, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-4 Diisostearate /Polyhydroxystearate/Sebacate, Sorbic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Product label

SAFE SEA[®]
MINERAL
Clear Zinc Sunscreen

30_{SPF}

JELLYFISH & SEA LICE BARRIER **FRIEND OF THE SEA[®]**
Certified

Fragrance Free
Coral Reef Safe
For Sensitive Skin
UVA/UVB Broad Spectrum
Water-resistant 40 minutes

3.4 FL OZ (100 mL)

SAFE SEA[®]
SPF 30 MINERAL Sunscreen
Non-Nano Zinc Oxide

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Inactive ingredients: Benzoic Acid, Benzyl Alcohol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Calcium Chloride, Caprylic / Capric triglyceride, Chlorphenisine, Dehydroacetic Acid, Dibutyl Adipate, Hydrogenated Castor Oil, Lanthanum Chloride, Magnesium Chloride, Magnesium Stearate, Panthenol, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-4 Diisostearate /Polyhydroxystearate/Sebacate, Sorbic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water	

Questions or comments?
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Made in Israel
Distributed by Nidaria Technology Ltd . 420
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Suite 2400, New York, New York 10170 US
Patents No. 6338837 / 6406709 / 6132747.

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zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65435-0600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PANTHENOL (UNII: WW9CM0067Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LANTHANUM CHLORIDE (UNII: 04M8624OXV)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045VJ989B)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65435-0600-1	100 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/01/2025	

Labeler - Nidaria Technology Ltd. (514977487)

Establishment

Name	Address	ID/FEI	Business Operations
Anna Lotan Ltd.		600458368	manufacture(65435-0600)

Revised: 11/2025

Nidaria Technology Ltd.