

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

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**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<sub>SPF</sub>**

**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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<b>Uses:</b> ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.	
<b>Warning:</b> ■ <i>For external use only</i> ■ <i>Do not use</i> on damaged or broken skin ■ <i>When using this product</i> keep out of eyes. Rinse with water to remove ■ <i>Stop use and ask a doctor</i> if rash occurs ■ <i>Keep out of reach of children.</i> If product is swallowed, get medical help or contact a Poison Control Center right away.	
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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

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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	

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**Labeler** - Nidaria Technology Ltd. (514977487)

**Establishment**

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

Revised: 11/2024

Nidaria Technology Ltd.