

## **SAFE SEA SPF 50 MINERAL- 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.*

-----

### **Drug Facts**

#### **Active ingredient**

Zinc oxide 21%

#### **Purpose**

Sunscreen

#### **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 be considered a recommendation to go into jellyfish infested water, nor is it guarantee against stings.
- In case of stings 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.

#### **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 80 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours
- Sun protection Measure- Spending time in the sun increase your 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 10a.m. to 2 p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months : Ask a doctor

## **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

## **Inactive ingredients**

Benzoic acid, Benzyl alcohol, Bis-Octyldodecyl, Dimer Dilinoleate/ Propanediol copolymer, Butyloctyl Salicylate, C12 -15 Alkyl benzoate, Calcium chloride, Caprylic / Capric triglyceride, Chlorphenesin, Dehydroacetic acid, Dibutyl Adipate, Hydrogenated Caster oil, Isopropyl Myristate, Lanthanum chloride, Magnesium Chloride, Magnesium stearate, Panthenol, Polyglycerly-2Dipolyhydroxystearate, Sorbic acid, Tocopheryl Acetate, Triethoxycaprylylsilane, water.

## **Product label**

# SAFE SEA®

## SPF 50 MINERAL Sunscreen

### Drug Facts

**Active ingredients:** Zinc Oxide 21%, **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 skin aging caused by the sun.

**Warning:** ■ *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 80 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, Bis-Octyldecyl Dimer Dilinoleate/Propanediol Copolymer, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Calcium Chloride, Caprylic / Capric triglyceride, Chlorphenesin, Dehydroacetic Acid, Dibutyl Adipate, Hydrogenated Castor Oil, Isopropyl Myristate, Lanthanum Chloride, Magnesium Chloride, Magnesium Stearate, Panthenol, Polyglyceryl-2 Dipolyhydroxystearate, Sorbic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water



Questions or comments?  
mail@nidaria.com

Made in Israel; Distributed by Nidaria Technology Ltd., 420 Lexington Avenue, Suite 2400, New York, New York 10170 US  
Patents No. 6338837 / 6406709 / 6132747.

# SAFE SEA®

## MINERAL

## Clear Zinc Sunscreen

# 50<sub>SPF</sub>



Certified

**Fragrance Free**  
**Coral Reef Safe**  
**For Sensitive Skin**  
**UVA/UVB Broad Spectrum**  
**Water-resistant 80 minutes**

2 FL OZ (60 mL)

## SAFE SEA SPF 50 MINERAL

zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65435-0400
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	210 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
PANTHENOL (UNII: W9CM0067Z)	
.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: X045WJ989B)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65435-0400-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	06/20/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/20/2023	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetics & Cleaners International, LLC. DBA C&C Industries		018949897	manufacture(65435-0400)

Revised: 6/2023

Nidaria Technology Ltd.