# SAFE SEA SPF 50 KIDS- homosalate, octocrylene, octisalate, avobenzone lotion NIDARIA TECHNOLOGY LTD

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## Safe Sea Sunscreen 50 SPF KIDS

# : Active Ingredients

Octocrylene 10%

Homosalate 10%

Octisalate 5%

Avobenzone 3%

: Sunscreen **Purpose** 

- : 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. **Uses**
- : ■ 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 **WarningFor external use only**
- : 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. **Directions**
- . If product is swallowed, get medical help or contact a Poison Control Center right away. **Keep out of reach of children**
- : 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. **Other Information**
- : Aqua, Dibutyl Adipate, Polyglyceryl 2 Dipolyhydroxystearate, Stearyl Dimethicone, Cetyl Dimethicone, Magnesium Stearate, Hydrogenated Castor Oil, Benzyl alcohol, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Glycosaminoglycans, Glycoproteins,

Plankton Extract, Parfum(Fragrance), Chlorphenisin, Panthenol, Tocopheryl Acetate, Dehydroacetic Acid, Benzoic Acid, Sorbic Acid **Inactive Ingredients** 

## Questions or comments?

mail@nidaria.com

# **Principal Display Panel**

Front Label





# SPF 50+ Marine Friendly Sunscreen

- Marine Friendly
- For Sensitive skin
- Water Resistant 80 min.
  - Oxibenzone & Octinoxate Free

#### Drug facts Purpose:

#### Active ingredients:

Octocrylene 10%, Homosalate 10%, Octisalate 5%, Avobenzone 3% 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.

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#### Questions or comments? mail@nidaria.com

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## SAFE SEA SPF 50 KIDS

homosalate, octocrylene, octisalate, avobenzone lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65435-0200

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	100 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LANTHANUM CHLORIDE (UNII: 04M8624OXV)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	
PHAEODACTYLUM TRICORNUTUM (UNII: Y5W63E7HLV)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T)	

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:65435- 0200-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2021	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	04/30/2021		

# Labeler - NIDARIA TECHNOLOGY LTD (514977487)

# **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
Filltech USA, LLC		926433855	manufacture(65435-0200)

Revised: 11/2023 NIDARIA TECHNOLOGY LTD