SAFE SEA SPF 40- octocrylene, homosalate, ethylhexyl salicylate, butyl methoxydibenzoylmethane liquid NIDARIA TECHNOLOGY LTD

Safe Sea Sunscreen 40 SPF

: Active Ingredients

Octocrylene 10%

Homosalate 10%

Octisalate 5%

Avobenzone 3%

: Sunscreen **Purpose**

: Aqua, Dibutyl Adipate, C12-15 Alkyl Benzoate, Cyclopentasiloxane, Dicaprylyl Ether, PEG-30 Dipolyhydroxystearate, Lauryl PEG/PPG-18/18 Methicone, Isopropyl Myristate, Stearyl Dimethicone, Cetyl dimethicone, Propylene Glycol, VP/Hexadecene Copolymer, Panthenol, Tocopheryl Acetate, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Plankton Extract, Glycoproteins, Glycosaminoglycans, Parfum, Chlorphenisin. Inactive Ingredients

: ■ 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**

: \blacksquare Do not use on damaged or broken skin \blacksquare When using this product keep out of eyes. Rinse with water to remove \blacksquare 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

Product label





Jellyfish/Sea Lice Barrier

- Marine Friendly
- Hypoallergenic 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.

active ingredients: Inactive ingredients: Aqua, Dibutyl Adipate, C12-15 Alkyl Benzoate, Cyclopentasilloxane, Dicaprylyl Ether, PEG-30 Dipolyhydroxystearate, Lauryl PEG/PPG-18/18 Methicone, Isopropyl Myristate, Stearyl Dimethicone, Cetyl dimethicone, Propylene Glycol, VP/Hexadecene Copolymer, Panthenol, Tocopheryl Acetate, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Plankton Extract, Glycoproteins, Glycosaminoglycans, Parfum, Chlorphenisin.

Questions or comments? mail@nidaria.com

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SAFE SEA SPF 40

octocrylene, homosalate, ethylhexyl salicylate, butyl methoxydibenzoylmethane liquid

Product Information

HUMAN OTC DRUG NDC:65435-0300 **Product Type** Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	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)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
PANTHENOL (UNII: WW9CM0O67Z)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LANTHANUM CHLORIDE (UNII: 04M8624OXV)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
PHAEODACTYLUM TRICORNUTUM (UNII: Y5W63E7HLV)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T)	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:65435- 0300-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	01/01/2021		
3 1 3				

Labeler - NIDARIA TECHNOLOGY LTD (514977487)

Revised: 11/2023 NIDARIA TECHNOLOGY LTD