

CORAL ISLE SPF 50 MINERAL SUNSCREEN- titanium dioxide, zinc oxide lotion
Derma Care Research Labs, LLC

Coral Isle SPF 50 Mineral Lotion

Active Ingredients

Titanium Dioxide 4.4%, Zinc Oxide 4%

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.

Warnings

For external use only.

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

Stop use and ask a doctor if rash occurs.

Keep Out of Reach of Children.

If 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
- 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 risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Inactive Ingredients

Water, ethylhexyl palmitate, C12-15 alkyl benzoate, styrene/acrylates copolymer, glycerin, sorbitan olivate, cetyl PEG/PPG-10/1 dimethicone, dimethicone, aluminum starch octenylsuccinate, sodium chloride, silica, aloe barbadensis leaf extract, cucumis sativus (cucumber) fruit extract, mentha piperita (peppermint) leaf extract, punica granatum fruit juice, oryza sativa (rice) bran water, rosmarinus officinalis (rosemary) leaf extract, vitis vinifera (grape) seed extract, camellia sinensis leaf extract, ethylhexylglycerin, propanediol, disodium EDTA, phenoxyethanol, alumina, hydrogen dimethicone

Label

Coral Isle SPF 50 Mineral Sunscreen, 2 oz, NDC 72839-114-02



Drug Facts

Active ingredients	Purpose
Titanium Dioxide 4.5%	Sunscreen
Zinc Oxide 4%	Sunscreen

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Other information ■ protect this product from excessive heat and direct sun

Inactive ingredients Water, Ethylhexyl Palmitate, C12-15 Alkyl Benzoate, Styrene/Acrylates Copolymer, Glycerin, Sorbitan Olivatate, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Aluminum Starch Octenylsuccinate, Sodium Chloride, Silica, Aloe Barbadensis Leaf Extract, Cucumis Sativus (Cucumber) Fruit Extract, Mentha Piperita (Peppermint) Leaf Extract, Punica Granatum Fruit Juice, Oryza Sativa (Rice) Bran Water, Rosmarinus Officinalis (Rosemary) Leaf Extract, Vitis Vinifera (Grape) Seed Extract, Camellia Sinensis Leaf Extract, Ethylhexylglycerin, Propanediol, Disodium EDTA, Phenoxylethanol, Alumina, Hydrogen Dimethicone.



Questions or Comments? Call: 1-888-356-8899



Dist. by: Rocky Mountain Sunscreen, Arvada, CO 80004

www.coralisles.com

Coral Isle Baby SPF 50 Mineral, 2 oz, NDC 72839-114-12

OCEAN SAFE

BABY

Broad Spectrum SPF 50 Water Resistant (80 Minutes)

50

PURE MINERAL SUNSCREEN

DERMATOLOGIST RECOMMENDED

FREE OF:
Oxybenzone, Octinoxate, Gluten
Parabens, Fragrance and Dyes

NET WT 2oz (57g)

Drug Facts

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Dist. by: Rocky Mountain Sunscreen, Arvada, CO 80004

www.coralisles.com

Coral Isle SPF 50 Mineral Sunscreen, 6 oz, NDC 72839-114-06



OCEAN SAFE

SPF 50

PURE MINERAL SUNSCREEN

Broad Spectrum SPF 50
Water Resistant (80 Minutes)

DERMATOLOGIST RECOMMENDED

FREE OF:
**Oxybenzone, Gluten,
Octinoxate, Parabens,
Fragrance and Dyes**

NET WT 6oz (170g)

Drug Facts

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Titanium Dioxide 4.5%.....	Sunscreen
Zinc Oxide 4%	Sunscreen

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Ocean Safe Pure Mineral Sunscreen



Dist. by: Rocky Mountain Sunscreen, Arvada, CO 80004

www.coralisles.com

Coral Isle SPF 50 Baby Mineral Sunscreen, 6 oz, NDC 72839-114-16



OCEAN SAFE

BABY

SPF

50

PURE MINERAL SUNSCREEN

Broad Spectrum SPF 50 Water Resistant (80 Minutes)

DERMATOLOGIST RECOMMENDED

FREE OF:

Oxybenzone, Gluten Octinoxate, Parabens Fragrance and Dyes

NET WT 6oz (170g)

Drug Facts

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Ocean Safe Pure Mineral Sunscreen



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CORAL ISLE SPF 50 MINERAL SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ROSEMARY (UNII: IJ67X351P9)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
CUCUMBER (UNII: YY7C30VXJT)	
POMEGRANATE JUICE (UNII: 99S671U9KB)	
RICE BRAN, DEFATTED (UNII: H6597RO5A2)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-114-06	170 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2024	
2	NDC:72839-114-12	57 g in 1 TUBE; Type 0: Not a Combination Product	01/02/2024	
3	NDC:72839-114-02	57 g in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2024	
4	NDC:72839-114-16	170 g in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2024	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M020	05/23/2023	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-114)

Revised: 1/2024

Derma Care Research Labs, LLC