

REFLECTING MINERAL SUNSCREEN- zinc oxide, titanium dioxide lotion

Helande, LLC

Active Ingredient(s)

Titanium Dioxide 2.35%, Zinc Oxide 13.5%

Purpose:

Sunscreen.

WARNINGS

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Use(s):

- 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 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:

- Shake well before use.
- Apply liberally and evenly 15 minutes before sun exposure.
- Use a water-resistant sunscreen if swimming or sweating.
- Reapply 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 10a.m.-2p.m.
- Wear long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor.

Inactive Ingredients:

Aqua (Water), C12-15 Alkyl Benzoate, Glycerin, Galactoarabinan, Ethylhexyl Palmitate, Argania Spinosa Kernel Oil, Tocopheryl Acetate (D-alpha), Caprylic/Capric Triglyceride, Polysorbate 60, Lithothamnion Calcareum Powder, Cetearyl Alcohol, Sodium Stearoyl Glutamate, Phenoxyethanol, Isostearic Acid, Coco-Glucoside, Xanthan Gum, Mannitol, Benzyl Alcohol, 1,2-Hexanediol, Caprylyl Glycol, Polyhydroxystearic Acid, Bisabolol (L-alpha), Alumina, Stearic Acid, Sodium Gluconate, Diatomaceous Earth, Caprylhydroxamic Acid, Ethylhexylglycerin, Zinc Sulfate, Tropolone, Maltodextrin, Camellia Sinensis (Green Tea) Leaf Extract, Camellia Sinensis (White Tea) Leaf Extract, Dimethylmethoxy Chromanol, Pollia Condensata Fruit Extract, Coenochloris Signiensis Extract, Lecithin, Ergothioneine

Other Information:

- Protect this product from excessive heat and direct sun.

<p>Inactive Ingredients: Aqua (Water), C12-15 Alkyl Benzoate, Glycerin, Galactoarabinan, Ethylhexyl Palmitate, Argania Spinosa Kernel Oil, Tocopheryl Acetate (D-alpha), Caprylic/Capric Triglyceride, Polysorbate 60, Lithothamnion Calcareum Powder, Cetearyl Alcohol, Sodium Stearoyl Glutamate, Phenoxyethanol, Isostearic Acid, Coco-Glucoside, Xanthan Gum, Mannitol, Benzyl Alcohol, 1,2-Hexanediol, Caprylyl Glycol, Polyhydroxystearic Acid, Bisabolol (L-alpha), Alumina, Stearic Acid, Sodium Gluconate, Diatomaceous Earth, Caprylhydroxamic Acid, Ethylhexylglycerin, Zinc Sulfate, Tropolone, Maltodextrin, Camellia Sinensis (Green Tea) Leaf Extract, Camellia Sinensis (White Tea) Leaf Extract, Dimethylmethoxy Chromanol, Pollia Condensata Fruit Extract, Coenochloris Signiensis Extract, Lecithin, Ergothioneine.</p> <p>Other Information: • Protect this product from excessive heat and direct sun.</p> <p>EU RP: CE.way, D04 FWD1, Dublin, IRL UK RP: CE.way, N17GU, UK Made in the USA. Manufactured for Helande, 2590 Healing Way, FL, 33543.</p> 	 HELANDE <i>Reflecting</i>		<p>Drug Facts</p> <p>Active Ingredient(s): Purpose: Sunscreen. Titanium Dioxide 2.35%, Zinc Oxide 13.5%.</p> <p>Use(s): • 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.</p> <p>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 swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS: • Shake well before use. • Apply liberally and evenly 15 minutes before sun exposure. • Use a water-resistant sunscreen if swimming or sweating. • Reapply 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.–2 p.m. • Wear long-sleeve shirts, pants, hats and sunglasses. • Children under 6 months: Ask a doctor.</p>	 <p>Helande: a sense of completeness in your skin, in your health, and in yourself.</p> <p>No matter where you are in life, achieving healthy skin is an essential step toward the confident, complete feeling we all seek. Our expertly-curated products give you what you need for at-home skincare that goes beyond the dermatology clinic.</p> <p>"As a dermatologist, I cannot stress enough the importance of daily sunscreen use. That's why I recommend our Reflecting Mineral Sunscreen—it's not only effective at protecting from harmful UVA and UVB rays but also specifically formulated for sensitive skin. We've designed it to feel light and sheer, eliminating that greasy or chalky feel, so you can enjoy comfortable, invisible protection every day."</p> <p><i>Dr. Amy Derick, MD</i></p>
Discover your Helande	Mineral Sunscreen Broad Spectrum SPF 30			
Helande.com	30 ML	1 FL. OZ.		

REFLECTING MINERAL SUNSCREEN

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85767-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.135 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.023 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
POLLIA CONDENSATA FRUIT (UNII: A3VS3MTE73)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
COENOCOLORIS SIGNIENSIS (UNII: G5P2RJVPDJ)	
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
COCO-GLUCOSIDE (UNII: ICS790225B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
ZINC SULFATE (UNII: 89DS0H96TB)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
WATER (UNII: 059QF0KO0R)	
GALACTOARABINAN (UNII: SL4SX1O487)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ARGANIA SPINOSA KERNEL OIL (UNII: 4V59G5UW9X)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
MANNITOL (UNII: 3OWL53L36A)	
ALUMINA (UNII: LMI26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROPOLONE (UNII: 7L6DL16P1T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BISABOLOS (UNII: 24WE03BX2T)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85767-610-01	1 in 1 BOX	07/01/2025	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2025	

Labeler - Helande, LLC (125307795)

Establishment

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. CoValence Laboratories		959735002	manufacture(85767-610)

Revised: 6/2025

Helande, LLC