

BETA-GLUCAN MILD SUNSCREEN- titanium dioxide, zinc oxide lotion
IUNIK Co., Ltd

BETA-GLUCAN MILD SUNSCREEN

ACTIVE INGREDIENTS

Titanium Dioxide 5.61%

Zinc Oxide 10.08%

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 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.

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.
 - 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 value 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-sleeved shirts, pants, hats, and sunglasses.
 - Children under 6 months of age: Ask a doctor.
 - Reapply at least every 2 hours.

- Use a water resistant sunscreen if swimming or sweating.

INACTIVE INGREDIENTS

Water, Dimethicone, Butyloctyl Salicylate, Neopentyl Glycol Diheptanoate, Glycerin, Trisiloxane, Silica, Isotridecyl Isononanoate, Trimethylsiloxysilicate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Methyl Trimethicone, Isostearyl Polyglyceryl-3 Dimethicone, Distearidimonium Hectorite, Stearic Acid, Aluminum Hydroxide, Magnesium Sulfate, 1,2-Hexanediol, Benzotriazolyl Dodecyl p-Cresol, Triethoxycaprylylsilane, Polyglyceryl-2 Dipolyhydroxystearate, Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Caprylyl Glycol, Hydroxypropyl Bispalmitamide MEA, Butylene Glycol, Pinus Densiflora Leaf Extract, Hydrogenated Lecithin, Bacillus Ferment, Cetearyl Alcohol, Beta-Glucan, Scutellaria Baicalensis Root Extract, Tremella Fuciformis Polysaccharide, Centella Asiatica Extract, Ceramide NP, Ceramide NG, Cholesterol, Phytosphingosine, Papaver Rhoëas Flower Extract, Ceramide AS, Ceramide AP, Ceramide EOP

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83403-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10.08 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.61 g in 100 mL

Inactive Ingredients				
Ingredient Name				Strength
DSTEARDIMONIUM HECTORITE (UNII: X687XDK09L)				
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)				
BACILLUS POLYFERMENTICUS (UNII: 6UQO3086C7)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
WATER (UNII: 059QF0KO0R)				
PINUS DENSIFLORA LEAF (UNII: Q1Q9P50WY)				
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)				
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9)				
CERAMIDE NG (UNII: C04977SRJ5)				
PAPAVER RHOEAS FLOWER (UNII: Y1MLS7E68X)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
TRISILOXANE (UNII: 9G1ZW13R0G)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
SILICA (UNII: ETJ7Z6XBU4)				
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)				
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)				
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
CETEARYL ALCOHOL (UNII: 2DMT128M1S)				
ODETIGLUCAN (UNII: Q6X9CNN54X)				
CERAMIDE AP (UNII: F1X8L2B00J)				
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)				
ISOTRIDECYL ISONONANOATE (UNII: WEF51750MT)				
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
MAGNESIUM SULFATE (UNII: DE08037SAB)				
1,2-HEXANEDIOL (UNII: TR046Y3K1G)				
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
HYDROXYPROPYL BISPALMITAMIDE MEA (UNII: EVX7NC9YVE)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)				
TREMELLA FUCIFORMIS WHOLE (UNII: 4938BNS0GU)				
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)				
CERAMIDE 4 (UNII: SF3LP91341)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
CERAMIDE NP (UNII: 4370DF050B)				
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)				
CERAMIDE 1 (UNII: 5THT33P7X7)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83403-101-	1 is 1 box	01/07/2026	

1	02	1 in 1 BOX	01/07/2020	
1	NDC:83403-101-01	60 mL in 1 TUBE; 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	01/07/2026	

Labeler - IUNIK Co., Ltd (695653625)

Establishment			
Name	Address	ID/FEI	Business Operations
UCL Co., Ltd.		696364043	manufacture(83403-101)