

PROTECTIF UNTINTED- zinc oxide and titanium dioxide cream
Derma Research Group Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Zinc Oxide 8.6 %

Titanium Dioxide 6.5 %

Purpose

Sun Protectant

Uses

Helps Prevent sunburn

Warning

For external use only.

Do not use

Do not use on damaged or broken skin

When using

When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

stop use

Discontinue use if rash or irritation develops or lasts. If irritation persists, consult a doctor

Keep out of reach of children

If swallowed get medical help or contact poison control center right away

Directions: Apply 15 minutes before sun exposure. 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 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-sleeve shirts, pants, hats and sunglasses.

NA

Inactive Ingredients:

Water (Aqua), Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclotetrasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Polysilicone-31, Glycerin, Aluminum Hydroxide, Stearic

Acid, Dimethicone/PEG-10/15 Crosspolymer,

Pyrus Malus (Apple) Fruit Extract, Sodium Chloride, Dipropylene Glycol, Sodium Citrate, Tocopherol, Dimethicone/Polyglycerin-3 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Tocopheryl Acetate, PEG/PPG-18/18 Dimethicone,

Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Cetearyl Olivinate, Sornitan Olivinate, Benzoic Acid, Ethylhexyl Palmitate, Silica Dimethyl Silylate,

Butylene Glycol, Pentylene Glycol, Sodium Hyaluronate, Cyclohexasiloxane, PEG-8, Ascorbyl Palmitate, Ascorbic Acid,

Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Ferrocyanide Decahydrate,

Hydroxytyrosol, Polygonum Aviculare Extract, Sodium Benzoate, Potassium Sorbate, Alcohol, Lecithin, Ectoin,

Cyclotetrapeptide-24 Aminocyclohexane Carboxylate, Carbomer, Polysorbate 20, Palmitoyl Tripeptide-1,

Palmitoyl Tetrapeptide-7, Vitis Vinifera (Grape) Fruit Cell Extract, Isomalt, Camellia Sinensis Leaf Extract,

Coffea Arabica (Coffee) Seed Extract, Citric Acid, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol

Protectif
MINERAL REPAIR WITH GMA7™
RÉPARATION MINÉRALE AVEC GMA7™
SPF 50+ FPS
sajic SKIN SCIENCE

Protectif
MINERAL REPAIR WITH GMA7™
RÉPARATION MINÉRALE AVEC GMA7™
SPF 50+ FPS
sajic SKIN SCIENCE

DERMA RESEARCH GROUP
33 Folly Drive, Guelph
ON N1L 0B7
Made in USA
Fabrique en USA
sajicskin.com

Drug Facts / Info-médicament

Active Ingredients Ingrédients Médicinaux	Purpose Objectif
Zinc Oxide 8.0%	Sun Protection/Ecran Solaire
Titanium Dioxide 6.5%	Sun Protection/Ecran Solaire

Warning: For external use only. Do not use on damaged or broken skin. When using this product, avoid contact with the eyes. If contact occurs, rinse thoroughly with water. Discontinue use if rash, irritation, development of spots, or irritation persists. Consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center immediately.
Mises en garde: Pour usage externe seulement. Ne pas utiliser sur la peau endommagée ou cassée. Lors de l'utilisation de ce produit, évitez le contact avec les yeux. En cas de contact, rincez les yeux à grande eau. Cessez d'utiliser le produit si une éruption cutanée ou une irritation se manifeste ou persiste. Si l'irritation persiste, consultez un médecin. En cas d'ingestion, consultez un médecin ou contactez un centre antipoisons immédiatement.

Directions: Apply 15 minutes before sun exposure. 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 value of 15 or higher and other sun protection measures including limiting time in the sun, especially from 10 a.m. to 2 p.m., wear long-sleeve shirts, pants, hats and sunglasses. **Dépend:** Appliquez la crème 15 minutes avant l'exposition au soleil. Réappliquez aux 2 heures au moins. **Protection quotidienne contre les rayons UV:** Passer du temps au soleil augmente votre risque de cancer de la peau et de vieillissement cutané précoce - pour réduire ce risque, utilisez régulièrement un écran solaire avec une valeur SPF à large spectre de 15 ou plus et d'autres mesures de protection solaire, y compris limiter le temps d'exposition au soleil, en particulier à partir de 10 heures matin à 14 heures, porter des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil.

Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Polysiloxane-11, Glycerin, Aluminum Hydroxide, Stearic Acid, Dimethicone/PEG-10/15 Crosspolymer, Pyrus Malus (Apple) Fruit Extract, Sodium Chloride, Dipropylene Glycol, Sodium Citrate, Tocopherol, Dimethicone/Polyglycerin-3 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Tocopheryl Acetate, PEG/PPG-18/18 Dimethicone, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Cetearyl Olivinate, Sornitan Olivinate, Benzoic Acid, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Pentylene Glycol, Sodium Hyaluronate, Cyclohexasiloxane, PEG-8, Ascorbyl Palmitate, Ascorbic Acid, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Sodium Ferrocyanide Decahydrate, Hydroxytyrosol, Polygonum Aviculare Extract, Sodium Benzoate, Potassium Sorbate, Alcohol, Lecithin, Ectoin, Cyclotetrapeptide-24 Aminocyclohexane Carboxylate, Carbomer, Polysorbate 20, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Vitis Vinifera (Grape) Fruit Cell Extract, Isomalt, Camellia Sinensis Leaf Extract, Coffea Arabica (Coffee) Seed Extract, Citric Acid, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol

Questions or Comments: Call 1-855-968-3600

PROTECTIF UNTINTED

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82038-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ALCOHOL (UNII: 3K9958V90M)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
APPLE (UNII: B423VGH5S9)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM FERROCYANIDE DECAHYDRATE (UNII: CG0CLR485X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYDROXYTYROSOL (UNII: QEU0NE4O90)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISOMALT (UNII: S870P55O2W)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
BENZOIC ACID (UNII: 8SKN0B0MIM)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
STEARIC ACID (UNII: 4ELV7Z65AP)
TOCOPHEROL (UNII: R0ZB2556P8)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE (UNII: NR327745KQ)
VITIS VINIFERA STEM (UNII: K1Z31TDY7Z)
ECTOINE (UNII: 7GXZ3858RY)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DIMETHICONE (UNII: 92RU3N3Y1O)
GLYCERIN (UNII: PDC6A3C0OX)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82038-004-02	1 in 1 CARTON	06/22/2022	
1	NDC:82038-004-01	100 g 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 final	M020	06/22/2022	

Labeler - Derma Research Group Inc. (200108372)