

PROTECTIF FAIR TINT- 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 Hydroxyhydrocinamate, Cetearyl Olivinate, Sorbitan Olivinate, Benzoic Acid, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol,

Pentylene Glycol, Sodium Hyaluronate, Cyclohexasiloxane, PEG-8, Ascorbyl Palmitate, Ascorbic Acid, Triethoxysilyethyl 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, Triethoxycaprylylsilane, Iron Oxides (CI 77491, CI 77492, CI 77499)

<p>Protectif™</p> <p>MINERAL REPAIR WITH GMA7™</p> <p>RÉPARATION MINÉRALE AVEC GMA7™</p> <p>SPF 50+ FPS LIGHT TINT</p> <p>sajic</p> <p>3.4 FL. OZ. e 100 mL SKIN SCIENCE</p>	<p>Drug Facts / Info-médicament</p> <table border="1"><thead><tr><th>Active Ingredients Ingrédients Médicinaux</th><th>Purpose Objectif</th></tr></thead><tbody><tr><td>Zinc Oxide 8.6%</td><td>Sun Protectant / Écran Solaire</td></tr><tr><td>Titanium Dioxide 6.5%</td><td>Sun Protectant / Écran Solaire</td></tr></tbody></table> <p>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 redness, 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.</p> <p>Mises en Garde: Pour usage externe seulement. Ne pas utiliser sur la peau endommagée ou cassée. Lors de l'utilisation de ce produit - éviter le contact avec les yeux. En cas de contact, rincer les yeux à grande eau. Cesser d'utiliser - le produit si une éruption cutanée ou une irritation se manifeste ou persiste. Si l'irritation persiste, consulter un médecin. En cas d'ingestion - consulter un médecin ou contacter un centre antipoisons immédiatement.</p> <p>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. / D'emploi: Appliquer la crème 15 minutes avant l'exposition au soleil. Réappliquer 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, utiliser 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 du matin à 14 h, porter des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil.</p> <p>Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, CI-15:1, Alkyl Benzoate, Dimethicone, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Polysiloxane-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 Hydroxyhydrocinamate, Cetearyl Olivinate, Sorbitan Olivinate, Benzoic Acid, Ethylhexyl Palmitate, Silica Dimethyl Silylate, Butylene Glycol, Pentylene Glycol, Sodium Hyaluronate, Cyclohexasiloxane, PEG-8, Ascorbyl Palmitate, Ascorbic Acid, Triethoxysilyethyl 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, Triethoxycaprylylsilane, Iron Oxides (CI 77491, CI 77492, CI 77499)</p> <p>Questions or Comments: Call toll free 1-855-968-3600</p>	Active Ingredients Ingrédients Médicinaux	Purpose Objectif	Zinc Oxide 8.6%	Sun Protectant / Écran Solaire	Titanium Dioxide 6.5%	Sun Protectant / Écran Solaire	<p>Protectif™</p> <p>MINERAL REPAIR WITH GMA7™</p> <p>RÉPARATION MINÉRALE AVEC GMA7™</p> <p>SPF 50+ FPS LIGHT TINT</p> <p>sajic</p> <p>3.4 FL. OZ. e 100 mL SKIN SCIENCE</p>	<p>Safeguard your skin from the sun with daily UV protection and skin nourishment. Natural minerals Zinc Oxide and Titanium Dioxide form a sun protective shield. Powerful extracts of Olive, Coffee Seed and Green Tea restoratively beautify the skin and help prevent UV damage. Our expert formulation is non-greasy, scent-free, and provides a makeup-friendly matte finish.</p> <p>Protégez votre peau du soleil avec une protection UV quotidienne et un soin nourrissant pour la peau. Les minéraux naturels de l'oxyde de zinc et de l'oxyde de titane forment un écran de protection solaire. Des extraits puissants d'olive, de graine de café et de thé vert embellissent la peau de manière réparatrice et aident à prévenir les dommages causés par les rayons UV. Notre formulation experte est non grasse, sans parfum et offre une finition mate idéale pour le maquillage.</p> <p>DERMA RESEARCH GROUP 33 Fairley Drive, Guelph ON N1L0B7 Made in USA Fabrique en USA</p> <p>sajicskin.com</p>
Active Ingredients Ingrédients Médicinaux	Purpose Objectif								
Zinc Oxide 8.6%	Sun Protectant / Écran Solaire								
Titanium Dioxide 6.5%	Sun Protectant / Écran Solaire								

PROTECTIF FAIR TINT

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82038-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
SILICA DIMETHYL Silylate (UNII: EU2PSP0G0W)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
VITIS VINIFERA STEM (UNII: K1Z31TDY7Z)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SODIUM FERROCYANIDE DECAHYDRATE (UNII: CG0CLR485X)	
HYDROXYTYROSOL (UNII: QEU0NE4O90)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE (UNII: 92RU3N3Y10)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
ISOMALT (UNII: S870P55O2W)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)
ALCOHOL (UNII: 3K9958V90M)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE (UNII: NR327745KQ)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9)
BENZOIC ACID (UNII: 8SKN0B0MIM)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
BUTYLENE GLYCOL (UNII: 3XUS85KORA)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
ECTOINE (UNII: 7GXZ3858RY)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
APPLE (UNII: B423VGH5S9)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82038-003-02	1 in 1 CARTON	06/22/2022	
1	NDC:82038-003-01	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)