

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

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**Drug Facts**

Active Ingredients: Zinc Oxide 8.6%, Titanium Dioxide 6.5%

Purpose: Sun Protectant

Uses: Broad spectrum (Sun Protection Factor 50 /SPF 50).

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 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: Adults and Children over 6 months of age: Apply generously and evenly 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 take other sun protection measures including limiting time in the sun, especially from 10 a.m. - 2 p.m., and wearing long-sleeve shirts, pants, hats and sunglasses

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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 Oliviate, Sorbitan Oliviate, 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 Deca hydrate, Hydroxytyrosol, Polygonum Aviculare Extract, Sodium Benzoate, Potassium Sorbate, Alcohol, Lecithin, Ectoin, Cyclotetra peptide-24 Aminocyclohexane Carboxylate, Carbomer, Polysorbate 20, Palmitoyl Tripeptide-1, Palmitoyl Tetra peptide-7, Vitis Vinifera (Grape) Fruit Cell Extract, Isomalt, Camellia Sinensis Leaf Extract, Coffee Arabica (Coffee) Seed Extract, Citric Acid, Phenoxyethanol,

# Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol

Protectif™

SPF 50+ FPS

BROAD SPECTRUM SUNSCREEN  
CRÈME SOLAIRE À LARGE SPECTRE

MINERAL REPAIR  
WITH GMA7™

RÉPARATION MINÉRALE  
AVEC GMA7™

UNTINTED  
UVA/UVB PROTECTION

sajic™

3.4 FL OZ @ 100 mL SKIN SCIENCE

Drug Facts / Info-médicament

<p><b>Active Ingredients</b> Ingrédients Médicinaux Zinc Oxide 8.6% Titanium Dioxide 6.5%</p>	<p><b>Purpose</b> Objectif Sun Protectant / Écran Solaire Sun Protectant / Écran Solaire</p>
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**Uses:** Broad spectrum (Sun Protection Factor 50 / SPF 50). **Directions:** Adults and Children over 6 months of age: Apply generously and evenly 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 take other sun protection measures including limiting time in the sun, especially from 10 a.m. – 2 p.m., and wearing long-sleeve shirts, pants, hats and sunglasses. / **Utilisations:** Large Spectre (Facteur de Protection Solaire / FPS 50). **D'emploi:** Adultes et enfants de plus de 6 mois : Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil. Renouvelez l'application au moins toutes les 2 heures. **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 prenez d'autres mesures de protection solaire, y compris la limitation du temps au soleil, en particulier de 10 h à 14 h et porter des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil.

**Warnings:** 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 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. **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 abondamment. Cesser d'utiliser si le produit cause 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 anti-poisons immédiatement.

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

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MINERAL REPAIR  
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UVA/UVB PROTECTION

sajic™

3.4 FL OZ @ 100 mL SKIN SCIENCE

Daily Protection Against UV Rays

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.

Skin and coral reef friendly.

Protection quotidienne contre les rayons UV

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 du dioxyde 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.

Sans danger pour la peau et les récifs coralliens.

NPN 80120156

**DERMA RESEARCH GROUP**  
33 Farley Drive, Guelph  
ON N1L0B7  
Made in USA  
Fabrique en USA

sajicskin.com

## PROTECTIF UNTINTED

zinc oxide and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82038-007
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)	
<b>HYDROXYTYROSOL</b> (UNII: QEU0NE4O90)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>PALMITOYL TETRAPEPTIDE-7</b> (UNII: Q41S464P1R)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72)	
<b>SODIUM FERROCYANIDE DECAHYDRATE</b> (UNII: CGOCLR485X)	
<b>POLYGONUM AVICULARE TOP</b> (UNII: ZCD6009IUF)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE</b> (UNII: NR327745KQ)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>PALMITOYL TRIPEPTIDE-1</b> (UNII: RV743D216M)	
<b>WINE GRAPE</b> (UNII: 3GOV20705G)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S)</b> (UNII: RLA2U05Z4Q)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>POLYSILICONE-15</b> (UNII: F8DRP5BB29)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER</b> (UNII: 2P2G24V6T9)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	

<b>TRIETHOXYSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE</b> (UNII: X75PL53TZJ)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ECTOINE</b> (UNII: 7GXZ3858RY)	
<b>ISOMALT</b> (UNII: S870P55O2W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82038-007-02	1 in 1 CARTON	05/17/2024	
1	NDC:82038-007-01	100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:82038-007-04	1 in 1 CARTON	05/17/2024	
2	NDC:82038-007-03	30 g in 1 BOTTLE, PUMP; 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	05/17/2024	

**Labeler** - Derma Research Group Inc. (200108372)

Revised: 6/2024

Derma Research Group Inc.