

**PROTECTIF DEEP 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.*

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**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 on damaged or broken skin.

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 am to 2 pm 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><b>Protectif™</b></p> <p>MINERAL REPAIR WITH GMA7™</p> <p>RÉPARATION MINÉRALE AVEC GMA7™</p> <p>SPF 50+ FPS DARK TINT</p> <p><b>sajic™</b></p> <p>3.4 FL. OZ e 100 mL SKIN SCIENCE</p> | <p><i>Drug Facts / Info-médicament</i></p> <table border="1"><thead><tr><th>Active Ingredients<br/>Ingrédients Médicinaux</th><th>Purpose<br/>Objectif</th></tr></thead><tbody><tr><td>Zinc Oxide 8.4%</td><td>Sun Protectant / Ecran Solaire</td></tr><tr><td>Titanium Dioxide 6.5%</td><td>Sun Protectant / Ecran Solaire</td></tr></tbody></table> <p><b>Warning:</b> 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.</p> <p><b>Mises en garde:</b> 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><b>Directions:</b> Apply 15 minutes before sun exposure. Reapply at least every 2 hours. <b>Sun Protection Measures:</b> 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. <b>Tips:</b> Appliquer la crème 15 minutes avant l'exposition au soleil. Réappliquer aux 2 heures au moins. <b>Protection quotidienne contre les rayons UV:</b> 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 du matin à 14 h, portez des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil.</p> <p><b>Inactive Ingredients:</b> 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> <p>Questions or Comments: Call toll free 1-855-968-3600</p> | Active Ingredients<br>Ingrédients Médicinaux | Purpose<br>Objectif | Zinc Oxide 8.4% | Sun Protectant / Ecran Solaire | Titanium Dioxide 6.5% | Sun Protectant / Ecran Solaire | <p><b>Protectif™</b></p> <p>MINERAL REPAIR WITH GMA7™</p> <p>RÉPARATION MINÉRALE AVEC GMA7™</p> <p>SPF 50+ FPS DARK TINT</p> <p><b>sajic™</b></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 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.</p> <p><b>DERMA RESEARCH GROUP</b><br/>33 Farley Drive, Guelph<br/>ON N1L0B7<br/>Made in USA<br/>Fabrique en USA</p> <p>sajicskin.com</p>  |
|---|--|--|---------------------|-----------------|--------------------------------|-----------------------|--------------------------------|---|---|
| Active Ingredients<br>Ingrédients Médicinaux  | Purpose<br>Objectif  |  |                     |                 |                                |                       |                                |   |   |
| Zinc Oxide 8.4%   | Sun Protectant / Ecran Solaire   |  |                     |                 |                                |                       |                                |   |   |
| Titanium Dioxide 6.5%   | Sun Protectant / Ecran Solaire   |  |                     |                 |                                |                       |                                |   |   |

**PROTECTIF DEEP TINT**  
zinc oxide and titanium dioxide cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:82038-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <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

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)  |                 |
| <b>APPLE</b> (UNII: B423VGH5S9)   |                 |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |                 |
| <b>CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE</b> (UNII: NR327745KQ)                         |                 |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)   |                 |
| <b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)  |                 |
| <b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)                   |                 |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)  |                 |
| <b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS) |                 |
| <b>SILICA DIMETHYL Silylate</b> (UNII: EU2PSP0G0W)  |                 |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)                                    |                 |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)   |                 |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)   |                 |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)  |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)   |                 |
| <b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)  |                 |
| <b>ISOMALT</b> (UNII: S870P55O2W)   |                 |
| <b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)  |                 |
| <b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72)   |                 |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)   |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)  |                 |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)   |                 |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)   |                 |
| <b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)  |                 |
| <b>HYDROXYTYROSOL</b> (UNII: QEU0NE4O90)  |                 |
| <b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)  |                 |
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)  |                 |
| <b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)  |                 |
| <b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)  |                 |
| <b>SODIUM FERROCYANIDE DECAHYDRATE</b> (UNII: CG0CLR485X)   |                 |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)   |                 |
| <b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)  |                 |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)   |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |                 |
| <b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)   |                 |

|   |
|---|
| <b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)                                      |
| <b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)   |
| <b>ECTOINE</b> (UNII: 7GXZ3858RY)   |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)   |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)  |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)  |
| <b>DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER</b> (UNII: 2P2G24V6T9)                         |
| <b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)  |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)  |
| <b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)   |
| <b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)                              |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)   |
| <b>POLYGONUM AVICULARE TOP</b> (UNII: ZCD6009IUF)   |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)   |
| <b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)                          |
| <b>VITIS VINIFERA STEM</b> (UNII: K1Z31TDY7Z)   |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)   |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)      |
| <b>WATER</b> (UNII: 059QF0KO0R)   |
| <b>POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S)</b> (UNII: RLA2U05Z4Q) |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)  |
| <b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)  |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)  |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)   |
| <b>TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE</b> (UNII: X75PL53TZJ)    |
| <b>PALMITOYL TRIPEPTIDE-1</b> (UNII: RV743D216M)  |
| <b>PALMITOYL TETRAPEPTIDE-7</b> (UNII: Q41S464P1R)  |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82038-002-02 | 1 in 1 CARTON                                      | 06/21/2022           |                    |
| 1 | NDC:82038-002-01 | 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                                     | 06/21/2022           |                    |

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