

CLOAK SPF 50- 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

Medicinal Ingredients

Zinc Oxide 8.6%

Titanium Dioxide 6.5%

Purpose:

Sun Protectant

Uses / Indications

Helps prevent sunburn / if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer

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 - Apply liberally 15 minutes before sun exposure - Reapply at least every 2 hours.

For use on children less than 6 months of age, consult a health care professional.

Inactive ingredients

Water, 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 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).

Imp. by Derma Research Group Canada. Made in the USA of US and/or Imported
 Ingredients Questions? 1-855-968-3600.
 www.dermaresearch.com

Make yourself invisible to the sun and father time.

Daily Protection Against UV Rays & Post Procedure Repair
 Powerful extracts of Olive Oil, Coffee Seed, and Green Tea provide natural skin repair and condition the skin. Physical barriers protect from the effects of the sun and UV rays.

The sun may cause sunburn, premature aging of the skin and skin cancer. Avoiding the sun, wearing protective clothing and regular use of sunscreens may reduce the chances of these harmful effects. This is especially true post procedure, when the skin is sensitive to the effects of the sun.

For use on Face and Body of all skin types including the most sensitive. Non-greasy formula, applies on with a matt finish, makeup friendly. Scent Free.

Dermatologist formulated and approved using the latest research, stringent clinical controls and vigorous laboratory testing

Comme le fera une cape, ce produit vous rendra invisible contre les effets du soleil et du père Temps.

Protection quotidienne contre les rayons ultraviolets et réparation post-opératoire

De puissants extraits d'huile d'olive, de grain de café et de thé vert fournissent une réparation et une revitalisation de la peau. Des écrans protecteurs abritent la peau contre les effets du soleil et des rayons ultraviolets.

Le soleil peut causer des coups de soleil, un vieillissement prématuré de la peau ou le cancer de la peau. Éviter le soleil, porter des vêtements de protection et utiliser la crème solaire régulièrement peut réduire les chances de ces effets néfastes. Cette remarque vaut particulièrement après une opération, au moment où la peau est sensible aux effets du soleil.

Pour usage sur le visage et le corps de tous types de peau, incluant la plus des sensibles. Cette formule non grasse à effet matifiant est convenable avec le port du maquillage. Sans parfum.

Formulé par des dermatologues et approuvé à l'aide des dernières recherches, d'épreuves en clinique et d'essais en laboratoire rigoureux.

No Chemical Blockers or Fragrance - Skin and Coral reef friendly.

Sans Bloqueurs chimiques ou parfums - Sans danger pour la peau et les récifs coralliens.

NPN:
 LOT: _____

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DERMA RESEARCH GROUP



Drug Facts / Information sur le médicament

Medicinal Ingredients Ingredients Médicinaux (w/w)	Purpose/Objectif
Zinc Oxide 8.6%	Sun Protectant / Écran Solaire
Titanium Dioxide 6.5%	Sun Protectant / Écran Solaire

Uses / Indications

Helps prevent sunburn / Aide à prévenir les coups de soleil - SPF 50+ / FPS 50+ - 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 / Si utilisé tel qu'indiqué et avec d'autres mesures de protection contre le soleil (voir mode d'emploi), les chances de développer un cancer de la peau et le risque de vieillissement de la peau prématuré causé par l'exposition au soleil seront réduits.

Warnings / Mises en garde

For external use only. / Pour usage externe seulement.

Do not use on damaged or broken skin / ne pas utiliser sur la peau endommagée ou cassée.

When using this product - avoid contact with the eyes. If contact occurs, rinse thoroughly with water. / Lors de l'utilisation de ce produit - éviter le contact avec les yeux. En cas de contact, rincer les yeux à grande eau.

Discontinue use - if rash or irritation develops or lasts. If irritation persists, consult a doctor. / Cesser d'utiliser - le produit si une éruption cutanée ou une irritation se manifeste ou persiste. Si l'irritation persiste, consulter un médecin.

Keep out of reach of Children - if swallowed get medical help or contact Poison Control Center right away. / En cas d'ingestion - consulter un médecin ou contacter un centre antipoisons immédiatement.

Directions - Apply liberally 15 minutes before sun exposure - Reapply at least every 2 hours. / D'emploi - Appliquer la crème 15 minutes avant l'exposition au soleil - Reappliquer aux 2 heures au moins.

For use on children less than 6 months of age, consult a health care professional / Pour les enfants âgés de moins de 6 mois, consultez un professionnel de la santé

Inactive ingredients / Ingrédients inactifs

Water, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclohexasiloxane, 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 Oliviate, Sorbitan Oliviate, 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).



CLOAK SPF 50

zinc oxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82038-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	86 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	65 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CYCLOTETRAPEPTIDE-24 AMINOCYCLOHEXANE CARBOXYLATE (UNII: NR327745KQ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOMALT (UNII: S870P55O2W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SODIUM FERROCYANIDE DECAHYDRATE (UNII: CGOCLR485X)	
ECTOINE (UNII: 7GXZ3858RY)	
CARBOXPOLYMETHYLENE (UNII: 0A5MM307FC)	
WINE GRAPE (UNII: 3GOV20705G)	

BENZOIC ACID (UNII: 8SKN0B0MIM)
TOCOPHEROL (UNII: R0ZB2556P8)
APPLE (UNII: B423VGH5S9)
FERRIC OXIDE RED (UNII: 1K09F3G675)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
GLYCERIN (UNII: PDC6A3C0OX)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)
HYDROXYTYROSOL (UNII: QEU0NE4O90)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82038-001-10	113 g in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	09/13/2021		

Labeler - Derma Research Group Inc. (200108372)