

DAILY BEAUTY REGIMEN WITH TRIHEX TECHNOLOGY- titanium dioxide and zinc oxide

Alastin Skincare, Inc.

Daily Beauty Regimen with TriHex Technology®

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Titanium Dioxide 8.9%	Sunscreen
Zinc Oxide 3.4%	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs.
- **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months of age: Ask a doctor.

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 10am - 2pm
- Wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

Inactive Ingredients:

Water/Aqua/Eau, Cyclopentasiloxane, Dimethicone, Polyglyceryl-3

Polydimethylsiloxyethyl Dimethicone, Butylene Glycol, Aluminum Hydroxide, Stearic Acid, Thermus Thermophilus Ferment, PEG-9 Polydimethylsiloxyethyl Dimethicone, Sodium Chloride, Camellia Sinensis Leaf Extract, Hydroxymethoxyphenyl Decanone, Dunaliella Salina Extract, Asteriscus Graveolens Flower/Fruit/Leaf/Stem Extract, Ergothioneine, Ectoin, Squalane, Glycerin, Caprylic/Capric Triglyceride, Tocopherol, Tocopheryl Acetate, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethylhexylglycerin, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, PEG/PPG-18/18 Dimethicone, Triethoxycaprylylsilane, Sodium Citrate, Potassium Sorbate, Dipropylene Glycol, Phenoxyethanol, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

Other Information

- Protect the product in this container from excessive heat and direct sun. Store at room temperature 15° - 30°C (59° - 86°F).

Distributed by
Alastin Skincare® Inc., a Galderma Company
Carlsbad, CA 92010

PRINCIPAL DISPLAY PANEL - Kit Carton

ALASTIN®
SKINCARE

DAILY BEAUTY
REGIMEN

with TriHex Technology®

Designed to help restore and renew skin to
maintain a healthy, youthful appearance.



DAILY BEAUTY REGIMEN WITH TRIHEx TECHNOLOGY

titanium dioxide and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70604-050
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70604-050-00	1 in 1 CARTON	09/24/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	12 g
Part 2	1 BOTTLE, PLASTIC	53.2 mL
Part 3	1 BOTTLE, PUMP	14.8 mL
Part 4	1 TUBE	29.6 mL

Part 1 of 4

HYDRATINT PRO MINERAL BROAD SPECTRUM SUNSCREEN SPF

titanium dioxide and zinc oxide cream

Product Information

Item Code (Source)	NDC:70604-011
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.089 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.034 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z 4Q)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
1-(4-HYDROXY-3-METHOXYPHENYL)-DECAN-3-ONE (UNII: BO24ID7E9U)	
DUNALIELLA SALINA (UNII: F4O1DKI9A6)	
ERGOTHIONEINE (UNII: BDZ 3DQM98W)	
ECTOINE (UNII: 7GXZ3858RY)	
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TOCOPHEROL (UNII: R0ZB2556P8)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70604-011-00	12 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 drug	M020	09/24/2021	

Part 2 of 4

GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	OAT (UNII: Z6J799EAJK)	
INGR	ODETIGLUCAN (UNII: Q6X9CNN54X)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	PANTOLACTONE (UNII: J288D7O0JS)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
INGR	STANNIC OXIDE (UNII: KM7N50LOS6)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		53.2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 of 4

RESTORATIVE SKIN COMPLEX

moisturizing [skin care preparations (creams, lotions, powder, and sprays)] lotion

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
INGR	POLYACRYLATE-13 (UNII: FS2D4T67EA)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
INGR	PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
INGR	PALMITOYL TRIPEPTIDE-5 TRIFLATE (UNII: 4IV5XO4TGK)	
INGR	PALMITOYLLSYLVALYLDIAMINO BUTYROYLTHREONINE TRIFLUOROACETATE (UNII: CL9S2UKN56)	
INGR	PALMITOYLLSYLVALYLDIAMINO BUTYRIC ACID TRIFLUOROACETATE (UNII: 79390Q4BYV)	
INGR	ACETYL HEXAPEPTIDE-38 (UNII: XUJ27AR5LA)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	SWERTIA CHIRAYITA WHOLE (UNII: 98BFC3JT53)	
INGR	PEA PROTEIN (UNII: 7Q50F46595)	
INGR	ORNITHINE (UNII: E524N2IXA3)	
INGR	CERAMIDE NP (UNII: 4370DF050B)	
INGR	ERGOTHIONEINE (UNII: BDZ3DQM98W)	
INGR	DUNALIELLA SALINA (UNII: F4O1DKI9A6)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
INGR	OLIVE OIL (UNII: 6UYK2W1W1E)	
INGR	SOYBEAN OIL (UNII: 241ATL177A)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	BETAINE (UNII: 3SCV180C9W)	
INGR	SQUALANE (UNII: GW89575KF9)	
INGR	CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	LEVULINIC ACID (UNII: RYX5QG61EI)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	P-ANISIC ACID (UNII: 4SB6Y7DMM3)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14.8 mL 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
Cosmetic			

Part 4 of 4

ULTRA NOURISHING MOISTURIZER

moisturizing [skin care preparations (creams, lotions, powder, and sprays)] lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
INGR	PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	OAT (UNII: Z6J799EAJK)	
INGR	TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
INGR	RICE BRAN (UNII: R60QEP13IC)	
INGR	ROSEMARY (UNII: IJ67X351P9)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
INGR	GLYCERYL MONOOLEATE (UNII: C4YAD5F5G6)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SOY STEROL (UNII: PL360EPO9J)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	

INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	BETAINE (UNII: 3SCV180C9W)	
INGR	POLYACRYLATE-13 (UNII: FS2D4T67EA)	
INGR	POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		29.6 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	09/24/2021	

Labeler - Alastin Skincare, Inc. (085997348)

Revised: 12/2023

Alastin Skincare, Inc.