

HYDRATINT PRO MINERAL BROAD SPECTRUM SUNSCREEN SPF- titanium dioxide and zinc oxide cream
Alastin Skincare, Inc.

HydraTint Pro Mineral Broad Spectrum Sunscreen SPF

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 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

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 - 91 g Tube Carton

NDC 70604-11-02

HYDRATINT
PRO MINERAL
SUNSCREEN

ALASTIN[®]
SKINCARE

Broad Spectrum SPF 36 Sunscreen
Water Resistant (40 minutes)

Net Wt. 3.2 Oz. 91 g

0.75000

1.57813



NDC 70604-11-02

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ALASTIN.com

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405 | 6406-02

This tinted lightweight, all-mineral sunscreen helps protect the skin while providing a soft, glowing appearance.

Helps provide protection from:

- UVA/UVB rays
- Pollution
- Blue Light
- IR Rays

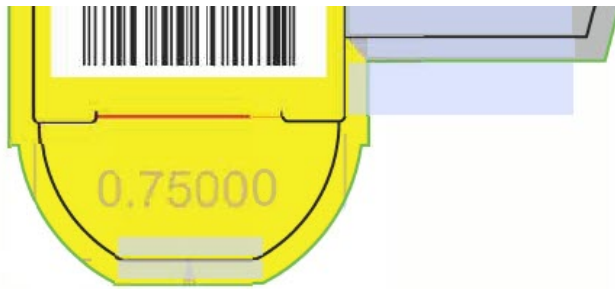


reef friendly

Does not contain Oxybenzone or Octinoxate

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HYDRATINT PRO MINERAL BROAD SPECTRUM SUNSCREEN SPF

titanium dioxide and zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | 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: RLA2U05Z4Q) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| 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: BDZ3DQM98W) | |
| 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 RED (UNII: 1K09F3G675) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |
| FERROSO FERRIC 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:70604-011-99 | 12 in 1 CARTON | 03/01/2022 | |
| 1 | | 6 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:70604-011-00 | 12 g in 1 TUBE; Type 0: Not a Combination Product | 03/01/2022 | |
| 3 | NDC:70604-011-02 | 1 in 1 CARTON | 03/01/2022 | |
| 3 | | 91 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:70604-011-04 | 130 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/01/2022 | |

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)

Registrant - Wasatch Product Development, LLC (962452533)