

**TONYMOLY MY SUNNY KIDS AND MOM SUN CREAM- other skin care preparations cream
Tonymoly Co., Ltd.**

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.

Active Ingredients

Dipropylene Glycol 7.00%, Titanium Dioxide 5.81%, Zinc Oxide 8.16%

Purpose

Sunscreen

Use

This mild daily sun cream moisturizes sensitive skin.

Caution

For external use only. Avoid contact with eyes. Keep out of reach of children. Discontinue use if signs of irritation and/or rash appear.

Keep out of reach of children

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Directions

During the last step of basic skin care, dispense an appropriate amount and evenly apply to any skin that will be exposed to ultraviolet sunlight.

Inactive Ingredients

WATER, CYCLOPENTASILOXANE, DICAPRYLYL CARBONATE, PEG-10 DIMETHICONE, CYCLOMETHICONE, DISTEARDIMONIUM HECTORITE, MAGNESIUM SULFATE, METHYL METHACRYLATE CROSSPOLYMER, ALUMINUM HYDROXIDE, ALUMINUM STEARATE, SORBITAN SESQUIOLEATE, PHENOXYETHANOL, METHICONE, CAPRYLYL GLYCOL, GLYCERYL CAPRYLATE, STEAROYL INULIN, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, FRAGRANCE, POLYGLYCERYL-6 POLYRICINOLEATE, MICROCRYSTALLINE CELLULOSE, DIMETHICONE, CELLULOSE GUM, BIOSACCHARIDE GUM-1, ANTHEMIS NOBILIS FLOWER WATER, ASPALATHUS LINEARIS LEAF EXTRACT, BETULA ALBA JUICE, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WATER, NELUMBO NUCIFERA FLOWER EXTRACT, TILIA VULGARIS FLOWER EXTRACT, BUTYLENE GLYCOL, BETA VULGARIS (BEET) ROOT EXTRACT, CHAMAECYPARIS OBTUSA LEAF EXTRACT, NYMPHAEA ALBA FLOWER EXTRACT, ALOE BARBADENSIS LEAF JUICE, GLYCERYL POLYMETHACRYLATE, PROPYLENE GLYCOL, MENTHYL PCA, ETHYL MENTHANE CARBOXAMIDE, AGARUM CRIBOSUM EXTRACT, CAPSOSIPHON FULVESCENS EXTRACT, CHLORELLA MINUTISSIMA EXTRACT, CODIUM FRAGILE EXTRACT, CODIUM TOMENTOSUM EXTRACT, CORALLINA OFFICINALIS EXTRACT, DUNALIELLA SALINA EXTRACT, ECKLONIA CAVA EXTRACT, ENTEROMORPHA

COMPRESSA EXTRACT, FUCUS VESICULOSUS EXTRACT, GELIDIUM CARTILAGINEUM EXTRACT, GELIDIUM SESQUIPEDALE EXTRACT, HIZIKIA FUSIFORME EXTRACT, HYDROLYZED SPONGE, JANIA RUBENS EXTRACT, LAMINARIA CLOUSTONI EXTRACT, LAMINARIA DIGITATA EXTRACT, LAMINARIA JAPONICA EXTRACT, PIKEA ROBUSTA EXTRACT, PLANKTON EXTRACT, PORPHYRA YEZOENSIS EXTRACT, SALICORNIA HERBACEA EXTRACT, SARGASSUM FULVELLUM EXTRACT, SEA CUCUMBER EXTRACT, SEA WHIP EXTRACT, SOLIDAGO VIRGAUREA (GOLDENROD) EXTRACT, SPIRULINA PLATENSIS EXTRACT, ULVA LACTUCA EXTRACT, ULVA PERTUSA EXTRACT, UNDARIA PINNATIFIDA EXTRACT, PLATINUM POWDER, POLYSORBATE 80

Principal Display Panel

TONYMOLY MY SUNNY KIDS AND MOM SUN CREAM

other skin care preparations cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59078-124 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 27466.56 mg in 60 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 14745.78 mg in 60 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LAMINARIA DIGITATA (UNII: 15E7C67EE8) | |
| CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG) | |
| ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| AGARUM CLATHRATUM (UNII: IW3259E99T) | |
| SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| MAGNESIUM SULFATE (UNII: DE08037SAB) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| ALUMINUM STEARATE (UNII: U6XF9NP8HM) | |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A) | |
| WATER (UNII: 059QF0K00R) | |
| BIO SACCCHARIDE GUM-1 (UNII: BB4PU4V09H) | |
| NYMPHAEA ALBA FLOWER (UNII: 40KQ7Q535O) | |
| NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ETHYL MENTHANE CARBOXYAMIDE (UNII: 6S7S02945H) | |
| PIKEA ROBUSTA (UNII: 1HL404JO0I) | |
| CAPSOSIPHON FULVESCENS (UNII: C59NK6GFJH) | |
| CHLORELLA MINUTISSIMA (UNII: 2DGH0N5419) | |
| CODIUM FRAGILE (UNII: MSE6FUU012) | |
| CODIUM TOMENTOSUM (UNII: B8B45BRU87) | |
| DUNALIELLA SALINA (UNII: F401DKI9A6) | |
| FUCUS VESICULOSUS (UNII: 535G2ABX9M) | |
| GELIDIUM CARTILAGINEUM (UNII: 37LBZ0E1UE) | |
| SPIRULINA PLATENSIS (UNII: 9L3TIHIUUE) | |
| ULVA LACTUCA (UNII: PHR3P25W6Y) | |

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| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| GELIDIUM SESQUIPEDALE (UNII: B487R5Z481) |
| UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S) |
| CORALLINA OFFICINALIS (UNII: 4004498D06) |
| CHAMAECYPARIS OBTUSA LEAF (UNII: 7OL154J5XB) |
| ECKLONIA CAVA (UNII: UXX2N5V39P) |
| PORPHYRA YEZOENSIS (UNII: D72A570T01) |
| SARGASSUM FULVELLUM (UNII: 245PL7LPSU) |
| SEA CUCUMBER, UNSPECIFIED (UNII: LUE8BK8H5Q) |
| SOLIDAGO VIRGAUREA WHOLE (UNII: F45YHM06JE) |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) |
| LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M) |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |
| BETULA PUBESCENS RESIN (UNII: 9G931M6I4G) |
| BEET (UNII: N487KM8COK) |
| SALICORNIA EUROPAEA (UNII: 6ADL50JAKW) |
| TILIA X EUROPAEA FLOWER (UNII: NHV2K10UDH) |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| MENTHYL PYRROLIDONE CARBOXYLATE, (-),DL- (UNII: 8P18J856U2) |
| ULVA COMPRESSA (UNII: SXZ209FM33) |
| SARGASSUM FUSIFORME (UNII: X436TJ4A11) |
| LAMINARIA HYPERBOREA (UNII: NXA595GQ1K) |
| LAMINARIA JAPONICA (UNII: WE98HW412B) |
| PLATINUM (UNII: 49DFR088MY) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59078-124-01 | 1 in 1 CARTON | 01/19/2016 | |
| 1 | | 60 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 |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 01/14/2016 | |

Labeler - Tonymoly Co., Ltd. (688216798)

Registrant - Tonymoly Co., Ltd. (688216798)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| Kolmar | | 688732723 | manufacture(59078-124) |