

**IMAGE PREVENTION PLUS PROFESSIONAL ULTIMATE PROTECTION
MOISTURIZER SPF50- homosalate, octisalate, octocrylene, zinc oxide
sunscreen cream
Swiss-American CDMO, LLC**

Image Prevention Plus Professional Ultimate Protection Moisturizer SPF50

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. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of Reach of Children

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Active Ingredients

Homosalate 10% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 6% Sunscreen

Zinc Oxide 9% Sunscreen

Uses

Helps prevent sunburn. 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.

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Directions For Sunscreen Use

Apply generously 15 minutes before sun exposure. Children under 6 months of age: ask a doctor. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Immediately after towel drying. 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 10am to 2pm, wear long-sleeved shirts, pants, hats and sunglasses.

Other Information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

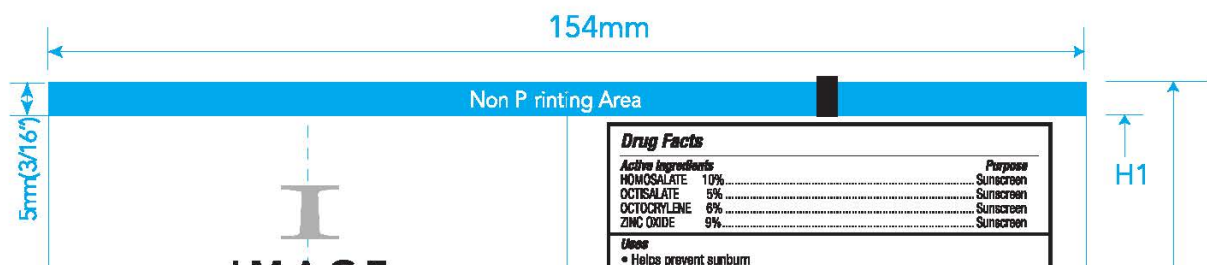
water, caprylic/capric triglyceride, glycerin, cyclopentasiloxane, cetyl PEG/PPG-10/1 dimethicone, thermus thermophilus ferment, polyacrylate-13, cetearyl ethylhexanoate, phenoxyethanol, polyisobutene, polyglyceryl-6 polyricinoleate, lecithin, isostearic acid, polyglyceryl-3 polyricinoleate, polyhydroxystearic acid, sodium chloride, cetearyl dimethicone, marrubium vulgare extract, helianthus annuus (sunflower) seed oil, disteardimonium hectorite, polysorbate 20, citrus aurantium dulcis (orange) peel oil, limonene, sorbitan isostearate, ethylhexylglycerin, panthenol, citrus nobilis (mandarin orange) peel oil, disodium EDTA, sodium hyaluronate, melanin, erythritol, citric acid, vanilla planifolia fruit extract, glucose, potassium sorbate, hydrolyzed pea protein, tocopherol, PEG-8/SMDI copolymer, tetrahexyldecyl ascorbate, tocopheryl acetate, barosma betulina (buchu) leaf oil, sodium benzoate, homarine HCL, pentaerythrityl tetra-di-t-butylhydroxyhydrocinnamate, sodium succinate, malus domestica fruit cell culture extract, arabidopsis thaliana (thale cress) extract, micrococcus lysate, plankton extract, ergothioneine

Questions

Questions: call 800-796-7546

Labeling

PREV PLUS ULTIMATE 50 PROFESSIONAL (PPUP-BB-001-US)
08.06.2019



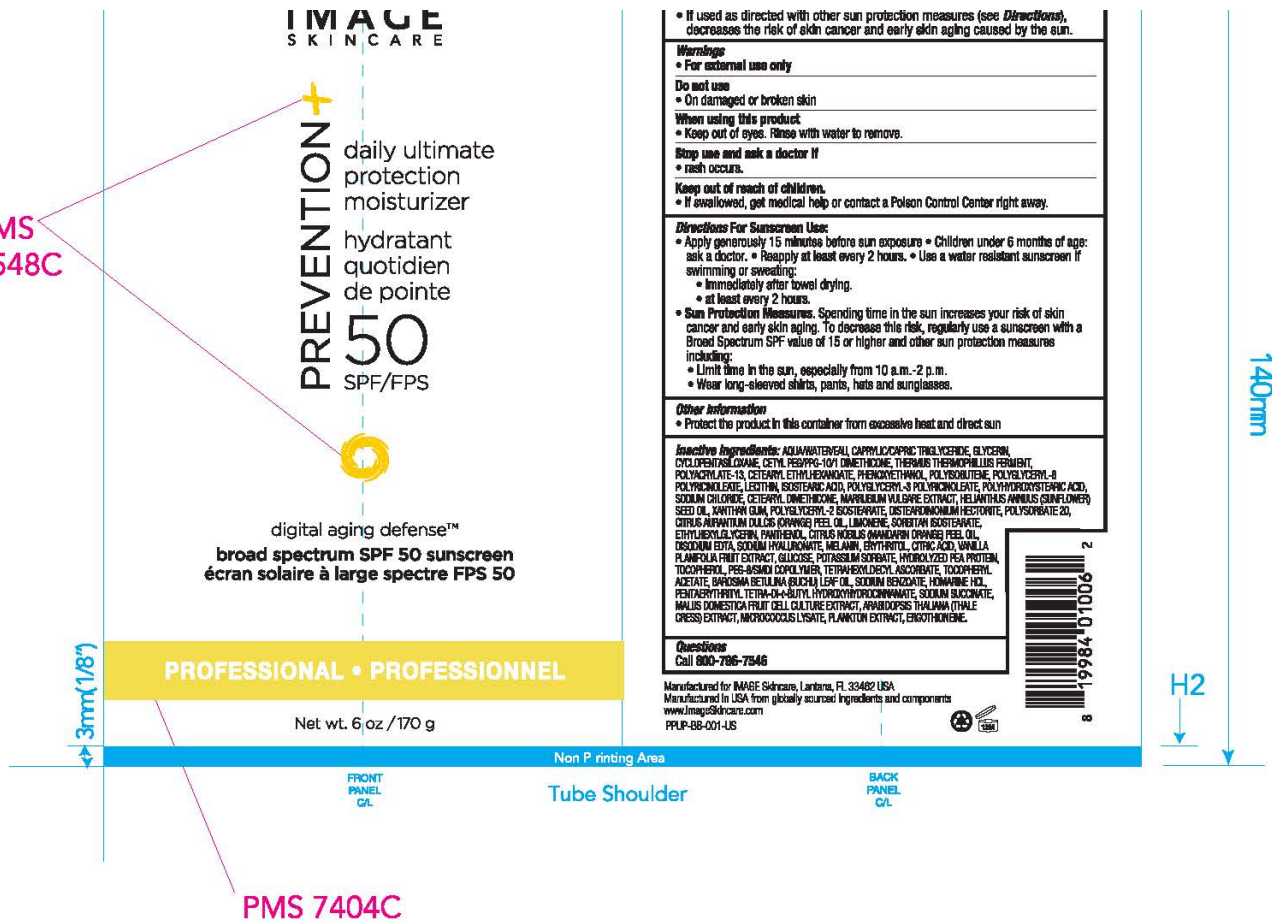


IMAGE PREVENTION PLUS PROFESSIONAL ULTIMATE PROTECTION MOISTURIZER SPF50

homosalate, octisalate, octocrylene, zinc oxide sunscreen cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60232-1026 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 110 g in 1000 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 g in 1000 g |
| OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM) | OCTOCRYLENE | 60 g in 1000 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 90 g in 1000 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X) | |
| THERMUS THERMOPHILUS (UNII: 415H64SACF) | |
| CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) | |
| MARRUBIUM VULGARE (UNII: 7A72MUN24Z) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| LIMONENE, (+/-)- (UNII: 9MC3I34447) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PANTHENOL (UNII: WW9CM0067Z) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| ERYTHRITOL (UNII: RA96B954X6) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| VANILLA BEAN (UNII: Q74T35078H) | |
| ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| TOCOPHEROL (UNII: ROZB2556P8) | |
| PEG-8/SMDI COPOLYMER (UNII: CCX72L6NY6) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| AGATHOSMA BETULINA LEAF OIL (UNII: KOS935A04V) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N) | |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) | |
| SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3) | |
| MALUS DOMESTICA WHOLE (UNII: 04W636S1V3) | |
| MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX) | |
| ERGOTHIONEINE (UNII: BDZ3DQM98W) | |

Product Characteristics

| | | | |
|---------------|-------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:60232-1026-6 | 170 g in 1 TUBE; Type 0: Not a Combination Product | 01/31/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 01/31/2020 | |

Labeler - Swiss-American CDMO, LLC (080170933)**Registrant** - Swiss-American CDMO, LLC (080170933)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|-------------------------|
| Swiss-American CDMO, LLC | | 080170933 | manufacture(60232-1026) |

Revised: 11/2023

Swiss-American CDMO, LLC