

IMAGE MD RESTORING LIP ENHANCER SPF15- sunscreen cream
Swiss-American CDMO, LLC

Image MD Restoring Lip Enhancer SPF15

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 doctor if rash occurs. If swallowed get medical help or contact a Poison Control Center right away.

Active Ingredients

Avobenzone 3.0% Sunscreen

Homosalate 10.0% Sunscreen

Octisalate 5.0% Sunscreen

Octocrylene 4.0% Sunscreen

Indications & Usage

Helps prevent sunburn. If used as directed with other sun protection measure (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Keep out of reach of children

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Directions

Apply liberally 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. Reapply 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 of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 am to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

Directions

Apply liberally 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. Reapply 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 of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 am

to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

Other information

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

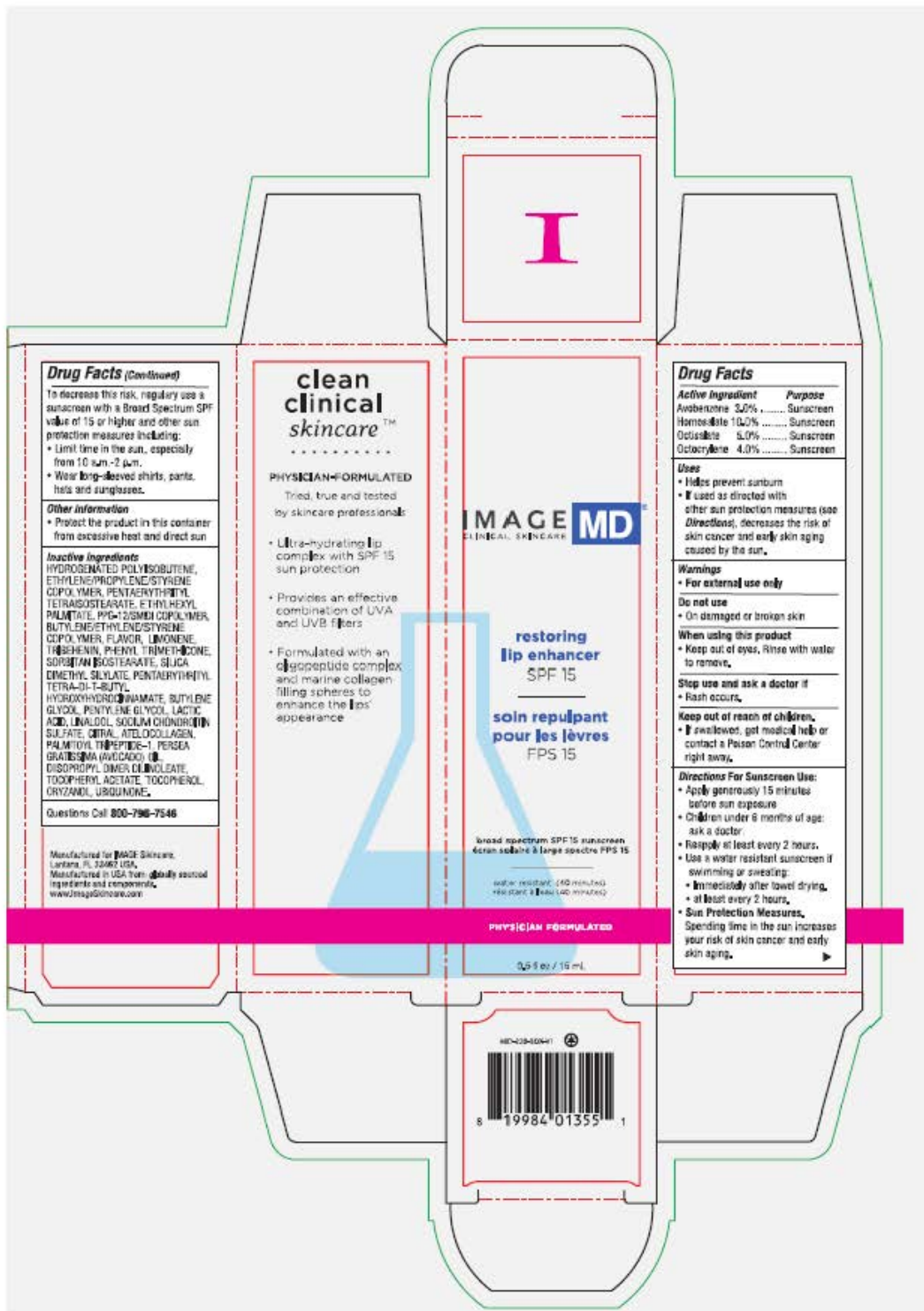
Inactive ingredients

hydrogenated polyisobutene, ethylene/propylene/styrene copolymer, Pentaerythrityl Tetraistearate, ethylhexyl palmitate, PPG-12/SMDI Copolymer, butylene/ethylene/styrene copolymer, flavor, limonene, tribehenin, phenyl trimethicone, sorbitan isostearate, silican dimethyl silylate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, butylene glycol, pentylene glycol, lactic acid, linalool, sodium chondroitin sulfate, citral, atelocollagen, palmitoyl tripeptide-1, Avacodo (Persea gratissima) Oil, Diisopropyl Dimer Dilinoleate, Tocopheryl Acetate, Tocopherol, Oryzanol, Ubiquinone.

Questions

Questions call 800-796-7546

Labeling



sunscreen cream

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60232-3537 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|-------------------|-----------------|
| Ingredient Name | Basis of Strength | Strength |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 g in 1000 g |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 g in 1000 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 100 g in 1000 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 40 g in 1000 g |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F) | |
| PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| TRIBEHENIN (UNII: 8OC9U7TQZ0) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| LACTIC ACID (UNII: 33X04XA5AT) | |
| LINALOOL, (+)- (UNII: F4VNO44C09) | |
| SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A) | |
| CITRAL (UNII: T7EU0O9VPP) | |
| PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ) | |
| PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS) | |
| DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR) | |
| ORYZANOL (UNII: SST9XCL51M) | |
| UBIDECARENONE (UNII: EJ27X76M46) | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:60232-3537-0 | 15 g in 1 TUBE; Type 0: Not a Combination Product | 03/17/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 03/17/2022 | |

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(60232-3537) |

Revised: 11/2023

Swiss-American CDMO, LLC