

**IMAGE PREVENTION REFINER PRIMER SPF50- zinc oxide, titanium dioxide  
sunscreen cream  
Swiss-American CDMO, LLC**

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**Image Prevention Refiner Primer 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**

Keep out of Reach of Children

**Active Ingredients**

Zinc Oxide 21% Sunscreen

Titanium Dioxide 5% 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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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.

**Directions**

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. Use a water resistant sunscreen when swimming or sweating, immediately after towel drying, at least every two 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**

idododecane, caprylic/capric triglyceride, butyloctyl salicylate, octyldodecyl neopentanoate, adipic acid/neopentyl glycol crosspolymer, lauryl dimethicone, polysilicone-11, propylene carbonate, silica cetyl silylate, dimethicone, stearammonium hectorite, glycerin, polyhydroxystearic acid, isostearic acid, lecithin, polyglyceryl-3 polyricinoleate, hydrogenated polyisobutene, polyglyceryl-4 diisostearate/polyhydroxystearate/sebacate, silica, water, helianthus annuus (sunflower) seed oil, citrus aurantium dulcis (orange) peel oil, limonene, tocopheryl acetate, gossypium hirsutum (cotton) extract, tetrahexyldecyl ascorbate, glucose, hydrolyzed pea protein, sodium chloride, glyconolactone, barosma betulina leaf oil, vanilla planifolia fruit extract, sodium benzoate, sodium succinate, calcium glyconate, iron oxides (CI77492, CI77491, CI77499)

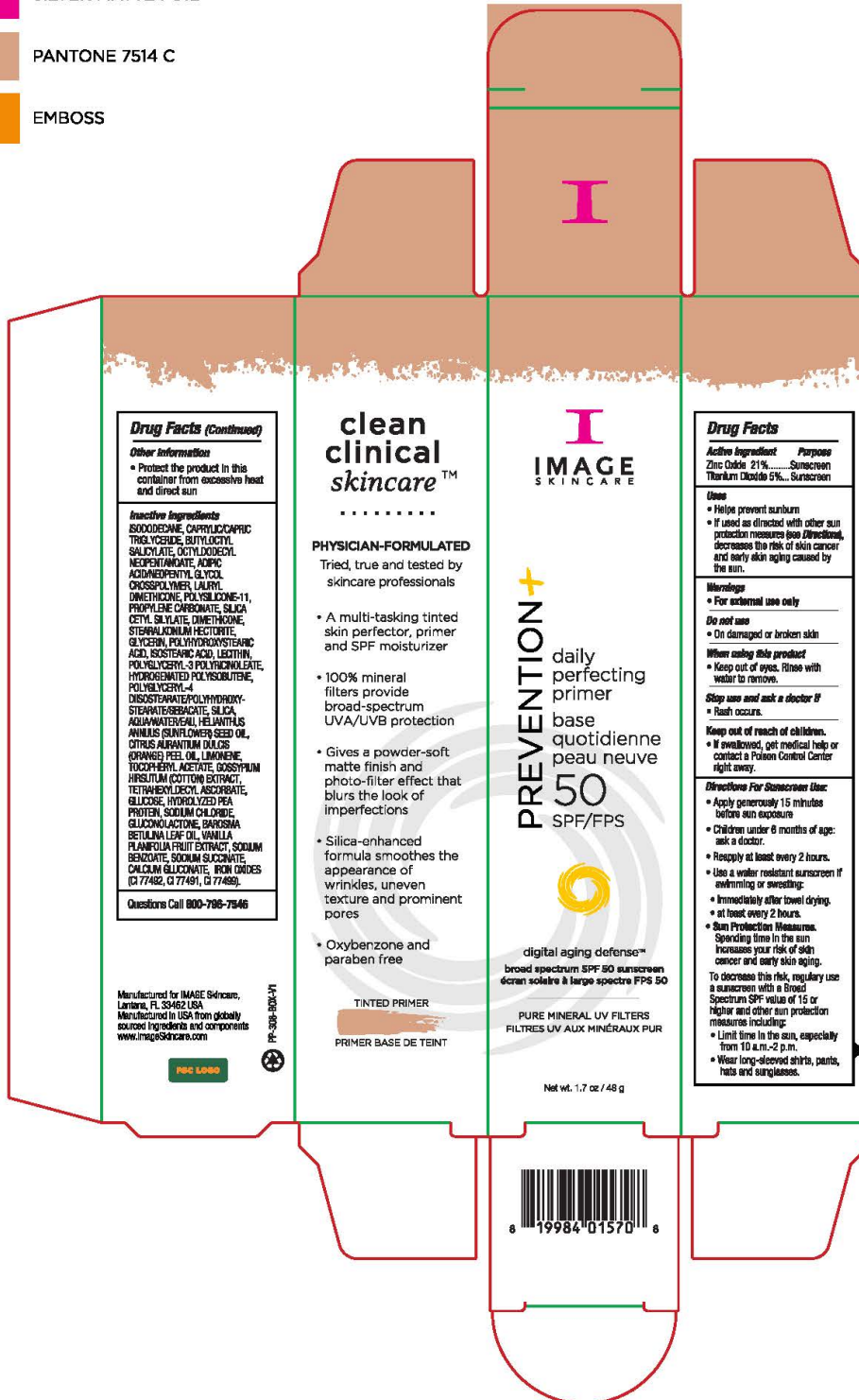
### **Questions**

Questions Call 800-796-7546

### **Labeling**

# PREVENTION+ - US Perfecting Primer Secondary

- PANTONE 7548 C
- SPOT UV GLOSS
- SILVER MATTE FOIL
- PANTONE 7514 C
- EMBOSS



**Drug Facts (Continued)**

**Other Information**

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

**Inactive Ingredients**

ISODODECANE, CAPRYLIC/CAPRIC TRIGLYCERIDE, BUTYLOCTYL SALICYLATE, OCTYLDODECYL NEOPENTANOATE, ADIPIC ACID/NEOPENTYL GLYCOL CROSSPOLYMER, LAURYL DIMETHICONE, POLYSILOXANE-11, PROPYLENE CARBONATE, SILICA SIZYL SILYLATE, DIMETHICONE, STEARALKONIAM HEPTOATE, GLYCERIN, POLYHYDROXYSTEARIC ACID, ISOSTEARIC ACID, LECITHIN, POLYGLYCERYL-3 POLYRICINOLATE, HYDROGENATED POLYSORBATE, POLYGLYCERYL-4 DISOSTEARATE/POLYHYDROXY-STERATE/SEBACATE, SILICA AQUAWATER/VEAL HELIANTHUS ANNUUS (SUNFLOWER SEED OIL, CITRUS ALBIPARTUM OIL) (ORANGE) PEEL OIL, LIMONENE, TOCOPHERYL ACETATE, GOSYPIUM HIRSUTUM (COTTON) EXTRACT, TETRAHEXYLDECYL ASCORBATE, GLUCOSE, HYDROLYZED PEA PROTEIN, SODIUM CHLORIDE, GLUCONOLACTONE, BAROSMA BETULINA LEAF OIL, VANILLA PLANIFOLIA FRUIT EXTRACT, SODIUM BENZOATE, SODIUM SUCCINATE, CALCIUM GLUCONATE, IRON OXIDES (CI 77492, CI 77491, CI 77489).

Questions Call 800-798-7946

**clean clinical skincare™**

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**PHYSICIAN-FORMULATED**

Tried, true and tested by skincare professionals

- A multi-tasking tinted skin perfecter, primer and SPF moisturizer
- 100% mineral filters provide broad-spectrum UVA/UVB protection
- Gives a powder-soft matte finish and photo-filter effect that blurs the look of imperfections
- Silica-enhanced formula smoothes the appearance of wrinkles, uneven texture and prominent pores
- Oxybenzone and paraben free

**IMAGE SKINCARE**

**PREVENTION+** daily perfecting primer base quotidienne peau neuve **50** SPF/FPS

digital aging defense™  
broad spectrum SPF 50 sunscreen  
écran solaire à large spectre FPS 50

PURE MINERAL UV FILTERS  
FILTRÉS UV AUX MINÉRAUX PUR

Net wt. 1.7 oz / 48 g

**Drug Facts**

**Active Ingredient Purpose**

Zinc Oxide 21%.....Sunscreen  
Titanium Dioxide 5%.....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.

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

**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 10 a.m.-2 p.m.
  - Wear long-sleeved shirts, pants, hats and sunglasses.

Manufactured for IMAGE Skincare, Lantana, FL 33462 USA  
Manufactured in USA from globally sourced ingredients and components  
www.imageSkincare.com

PRC 3038-802-01

**NET 1.7 OZ**



# IMAGE PREVENTION REFINER PRIMER SPF50

zinc oxide, titanium dioxide sunscreen cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60232-1830
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	210 g in 1000 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 g in 1000 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>STEARALKONIUM HECTORITE</b> (UNII: O LX698AH5P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>GOSSYPIUM HIRSUTUM WHOLE</b> (UNII: 0Z88765ZGC)	
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)	
<b>AGATHOSMA BETULINA LEAF OIL</b> (UNII: KOS935A04V)	
<b>VANILLA BEAN</b> (UNII: Q74T35078H)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

## Product Characteristics

<b>Color</b>	brown (tinted)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60232-1830-0	7 g in 1 TUBE; Type 0: Not a Combination Product	03/09/2020	
2	NDC:60232-1830-2	48 g in 1 TUBE; Type 0: Not a Combination Product	03/09/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/06/2020	

**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(60232-1830)

Revised: 11/2023

Swiss-American CDMO, LLC