

**SUNSCREEN FOR BABY SPF50PLUS- octocrylene, ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate lotion**  
**Guangzhou Senmai Biotechnology Co., Ltd.**

-----

**Active Ingredients**

Octocrylene 10%

Ethylhexyl methoxycinnamate 10%

Titanium Dioxide 8%

Ethylhexyl salicylate 5%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn

If used as directed with other sun protection measures, 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 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**

Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician. Reapply at least every 2 hours.

## **Precautions**

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 value of SPF 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. Children under 6 months of age: Ask a physician,

## **Other information**

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

## **Product Name**

Sunscreen for Baby SPF50plus

## **Inactive Ingredients**

Water, Glycerin, Dicaprylyl Carbonate, Isononyl Isononanoate, Caprylic/capric Triglyceride, Dimethicone, Ceryl PEG/PPG-10/1 Dimethicone, Butylene Glycol, Phenyl Trimethicone, Cyclopentasiloxane, Corn Gluten Amino Acids, Magnesium Stearate, Magnesium Sulfate, Tocopheryl Acetate, Quaternium-18 Bentonite, Hydroxyacetophenone, 1,2-hexanediol, Aluminum Hydroxide, Stearic Acid, Distearidimonium Hectorite, Fragrance, PropyleneCarbonate, BHT, Vitamin E

## **Manufacturer**

Guangzhou Senmai Biotechnology Co.

## **Address**

20-1second floor, 20-2 first to third floor, Dashan Road, Qinghu, Junhe Street, Baiyun district, Guangzhou City, China

## **Capacity**

30ml/1.05 Fl.oz

## **Shelf Life**

3 Years

## **Place of Origin**

Made in China

# PRINCIPAL DISPLAY PANEL



45x45x95mm

## SUNSCREEN FOR BABY SPF50PLUS

octocrylene, ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:84509-001

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3000 mg in 30 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2400 mg in 30 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3000 mg in 30 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1500 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRICAPRILIN</b> (UNII: 6P92858988)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)</b> (UNII: 035JKJ76MT)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>BENTOQUATAM</b> (UNII: 7F465U79Q1)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>AMINO ACIDS, CORN GLUTEN</b> (UNII: 0540V8ZD7V)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>FRAGRANCE 13576</b> (UNII: 5EM498GW35)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84509-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/11/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/11/2024	

**Labeler** - Guangzhou Senmai Biotechnology Co., Ltd. (707735253)

**Registrant** - Dongguan Xiaogoubeige trading company Ltd. (707735253)

### Establishment

Name	Address	ID/FEI	Business Operations
Dongguan Xiaogoubeige trading company Ltd.		707735253	label(84509-001) , manufacture(84509-001)

Revised: 1/2025

Guangzhou Senmai Biotechnology Co., Ltd.