

**SUNSCREEN FOR BABY SPF50PLUS- octocrylene, ethylhexyl methoxycinnamate, titanium dioxide, ethylhexyl salicylate lotion
Dongguan Xiaogoubeige trading company 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, Propylene Carbonate, BHT, Vitamin E

Manufacturer

Guangzhou Senmai Biotechnology Co.

Address

20-1 second 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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3000 mg in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2400 mg in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3000 mg in 30 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1500 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
WATER (UNII: 059QF0KO0R)	
TRICAPRILIN (UNII: 6P92858988)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BENZOQUATAM (UNII: 7F465U79Q1)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
AMINO ACIDS, CORN GLUTEN (UNII: 0540V8ZD7V)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	
MAGNESIUM STEARATE (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 - Dongguan Xiaogoubeige trading company 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: 7/2024

Dongguan Xiaogoubeige trading company Ltd.