

FATAZEN SUNSCREEN LIP BALM STICK- fatazen sunscreen lip balm stick lipstick

Guangzhou Guocui Biological Technology Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

83885-005

Active Ingredient(s)

Ethylhexyl salicylate
Octocrylene

Purpose

sunscreen

Use

Moisturizes and prevents sunburn

Warnings

For external use only.

Do not use

in children less than 2 months of age

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

Directions

Before going out, apply a sufficient amount of sunscreen lip balm on your lips to moisturize your lips and effectively prevent UV damage to your lips. Supervise children under 6 years of

age when using this product to avoid swallowing. Store between 15- 30C (59-86F)

Other information

No data

Inactive ingredients

Ethyhexyl palmitate, tridecyl trelliate, t disostetary malate, squalane, polyetylene, beeswax. phytosterals, tocopheryl acelate, (daily) fragrance



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83885-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	7 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SQUALANE (UNII: GW89575KF9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	
SITOSTEROLS (UNII: G7V636VTDY)	
HEXADIMETHRINE BROMIDE (UNII: 4C905MSK4W)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83885-005-01	5 g in 1 CANISTER; Type 0: Not a Combination Product	04/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/17/2024	

Labeler - Guangzhou Guocui Biological Technology Co., Ltd. (419547269)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Guocui Biological Technology Co., Ltd.		419547269	manufacture(83885-005)

Revised: 4/2024

Guangzhou Guocui Biological Technology Co., Ltd.