

**FRESH MINT MOISTURIZING SUNSCREEN LIP BALM SPF 15- ethylhexyl methoxycinnamate lipstick
Tween Brands Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Fresh Mint Moisturizing Sunscreen Lip Balm SPF 15

Active Ingredient

Ethylhexyl Methoxycinnamate 3.5%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warning

- 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 the reach of children

If product is swallowed get medical help or contact a Poison Control Center in area.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.

Inactive Ingredients

Mineral Oil, Ozokerite, Ethylhexyl Palmitate, Polybutene, Cera alba, Synthetic wax, Butyrospermum Parkii (Shea) Butter, Aloe Barbadensis Extract, Fragrance, Tocopheryl acerare.

Fresh Mint Moisturizing Sunscreen Lip Balm SPF 15

follow below for
lip balm color for both

191263



Moisturizing
SPF 15
flavored lip balm

cap



CHROME
SILVER



printing pattern on the plastic

FRESH

MINT

justshine
moisturizing
sunscreen lip balm
SPF15
net wt. 0.12 oz / 3.5 g

Justice
smile bright

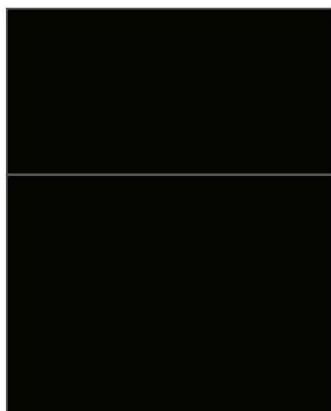
Drug Facts
Active Ingredients Ethylhexyl Methoxycinnamate 3.5% Purpose Sunscreen
Uses Helps prevent sunburn
Warnings For external use only Do not use on damaged or broken skin When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs Keep out of the reach of children, if product is swallowed get medical help or contact a Poison Control Center in area
Directions • apply liberally 15 minutes before sun exposure • reapply at least every 2 hours
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Distr. by/par Tween Brands
New Albany, OH 43054
Toronto, ON L6T 3R6
Made in China/Fab. Chine
191263 3363 08/16

5.7cm

2.2cm

2.2cm



justshine

PVC
WINDOW
SIZE: 2.3x5.7CM

Moisturizing
SPF 15
sunscreen lip balm

0.375" DIA.



Justice[™]
smile bright

FRESH MINT FLAVORED
SUNSCREEN LIP BALM

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FRESH MINT MOISTURIZING SUNSCREEN LIP BALM SPF 15

ethylhexyl methoxycinnamate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60637-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	122.5 mg in 3.5 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SHEA BUTTER (UNII: K49155WL9Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60637-116-00	1 in 1 BOX	09/02/2016	
1		3.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/02/2016	

Labeler - Tween Brands Inc (965758188)

