

**SWEET BERRY 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.

Sweet Berry 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.

Berry Moisturizing Sunscreen Lip Balm SPF 15

printing pattern on the plastic

SWEET

BERRY

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

2.2cm

Justice
smile bright

Drug Facts
Active Ingredients Ethylhexyl Methoxycinnamate 3.5%
Purpose Sunscreen
Uses Helps prevent sunburn
Warnings Do not use on damaged or broken skin For external use only 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
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Distr. by/par Tween Brands
New Albany, OH 43054
Toronto, ON L6T 3R5
Made in China/Fab. Chine
191264 3363 08/16

2.2cm

5.7cm

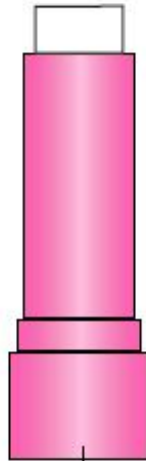
follow below for
lip balm color for both



Moisturizing
SPF 15
flavored lip balm

191264

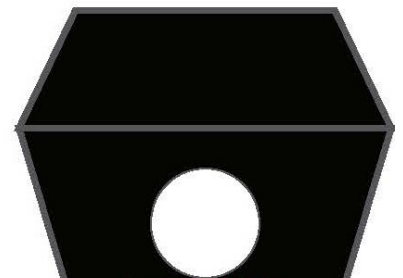
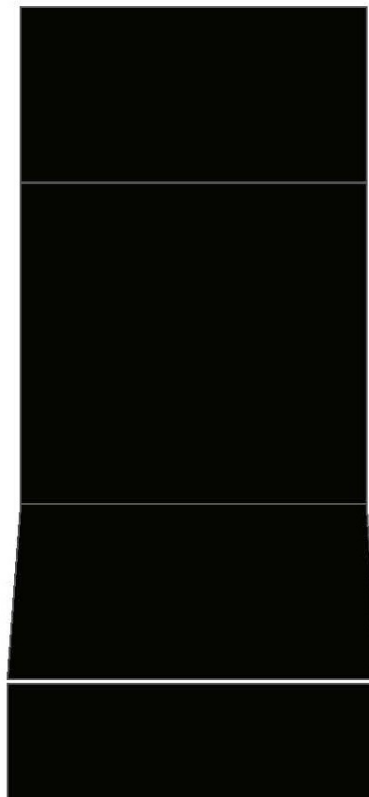
cap



CHROME
806C



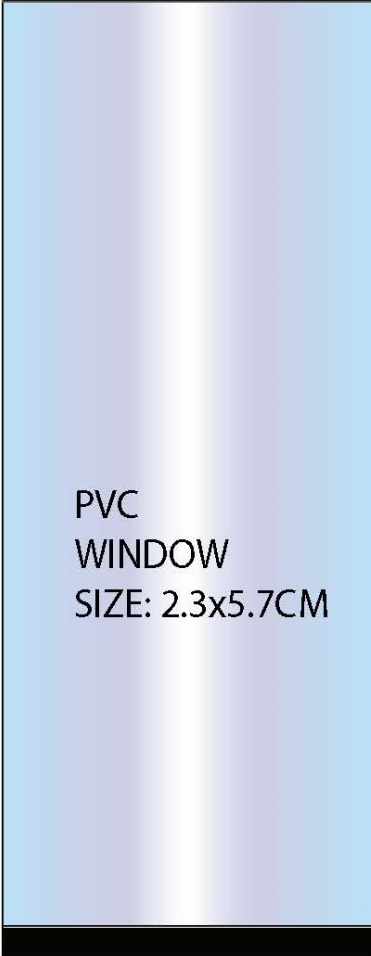
7.3cm



0.375" DIA.



justshine



PVC
WINDOW
SIZE: 2.3x5.7CM

Moisturizing
SPF 15
sunscreen lip balm

Justice[™]
smile bright

SWEET BERRY FLAVORED
SUNSCREEN LIP BALM

Drug Facts

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SWEET BERRY MOISTURIZING SUNSCREEN LIP BALM SPF 15

ethylhexyl methoxycinnamate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60637-115
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:60637-115-00	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)