

SKIN CRAVE SPF15 LIP BALM- spf15 lip balm (chemical) lipstick
Tropical Enterprises International, 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.

spf15 lip balm

Active Ingredients: Purpose: Sunscreen

Avobenzone (2.0%)

Octinoxate (6.5%)

Octisalate (5.0%)

Octocrylene (1.5%)

Purpose: Sunscreen

Uses: Helps prevent sunburn

Warnings:

- **Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- **For external use only**
- Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

- When using this product keep out of eyes. Rinse with water to remove.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

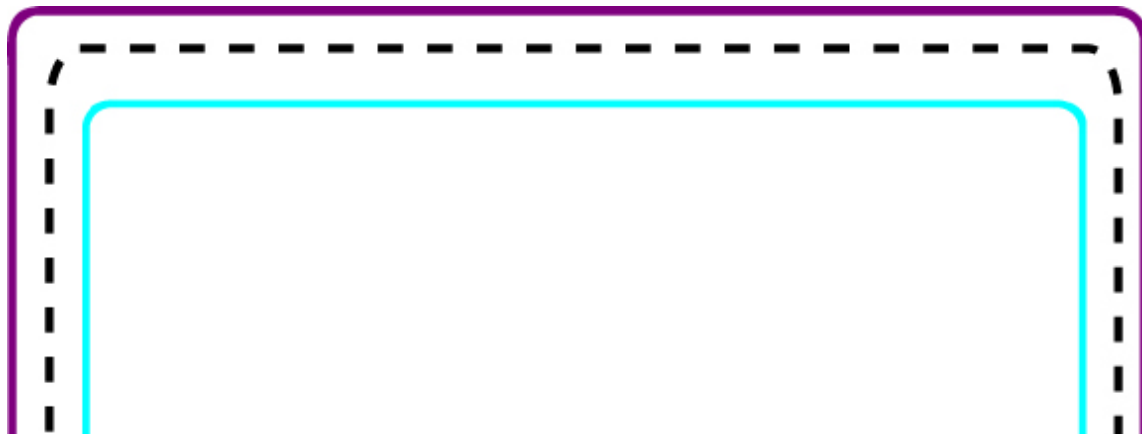
Directions:

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.

Inactive Ingredients: Sunflower oil, beeswax, extra virgin olive oil, flavor, hemp seed oil, rosemary extract, vitamin E, aloe vera

Other Information: Protect this product from excessive heat and direct sun.

Questions or Comments? 1-877-773-9800



SPF 15

Natural Flavor Lip Moisturizer

Distributed by: TMarketing • asi/92243 • Made in USA
Net Wt. 4.5g

Peel label for drug facts info ↷

DRUG FACTS

Active Ingredients:

Avobenzone (2.0%)	Sunscreen
Octinoxate (6.5%)	Sunscreen
Octisalate (5.0%)	Sunscreen
Octocrylene (1.5%)	Sunscreen

Purpose:

Uses: Helps prevent sunburn.

WARNINGS:

- **Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- **For external use only**
- Do not use on damaged or broken skin.
- **Stop use and ask a doctor** if rash occurs.
- When using this product keep out of eyes. Rinse with water to remove.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.

Inactive Ingredients: Sunflower Oil*, beeswax, extra virgin olive oil*, flavor, hemp seed oil*, rosemary extract, vitamin E, aloe vera.

Other Information: Protect this product from excessive heat and direct

Twist Cap to Break Seal

sun.

Questions or Comments? 1-877-773-9800

SKIN CRAVE SPF15 LIP BALM

spf15 lip balm (chemical) lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-295
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1.5 mg in 15 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mg in 15 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 15 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM, GRAPE, CITRUS, CHERRY, STRAWBERRY, BERRY, MINT, PEPPERMINT, VANILLA, WATERMELON, TROPICAL FRUIT PUNCH, POMEGRANATE, ROOT BEER, MANGO, COCONUT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-295-15	15 mL in 1 CANISTER; Type 0: Not a Combination Product	08/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2012	

Labeler - Tropical Enterprises International, Inc. (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose		083819404	manufacture(58418-295)

Revised: 7/2018

Tropical Enterprises International, Inc.