

LIP BALM - octinoxate oxybenzone dimethicone lipstick
Tri-Coastal Design Company 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.

Drug Facts

Active Ingredient

Octyl Methoxycinnamate 6%

Oxybenzone 6%

Dimethicone 1%

Purpose

Sunscreen

Skin Protectant

Uses

- Helps prevent sunburn
- Temporarily protects and relieves chapped lips

Warnings

- Keep out of eyes. Stop use if rash or irritation occurs. Keep out of reach of children. For external use only.

Directions

- Apply liberally before sun exposure and as needed.

Inactive Ingredients

BHA, BHT, Caprylic/Capric Triglyceride, Cera Microcristallina, Flavor, Lanolin, Mineral Oil (Paraffinum Liquidum), Ozokerite, Petrolatum, Phenyl Trimethicone, Polyethylene, Propylparaben, PVP/Eicosene Copolymer, Tocopheryl Acetate

Package Label

Package Label



SPF | **Lip Balm**
15 | **STANDARD**

TOTAL NET WT 0.6 oz (17.5 g)
 0.12 oz (3.5 g) each

Drug Facts

Active Ingredients	Purpose
Octyl Methoxycinnamate 6%, Oxybenzone 6%.....	Sunscreen
Dimethicone 6%	Skin Protectant

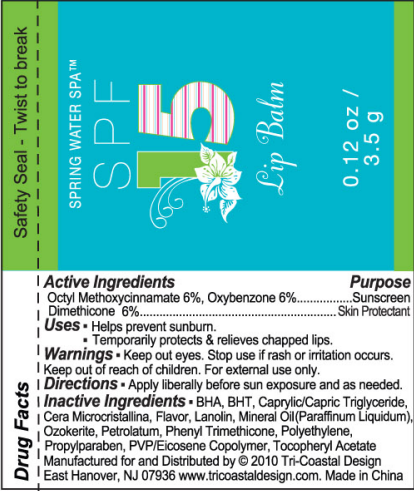
Uses ▪ Helps prevent sunburn.
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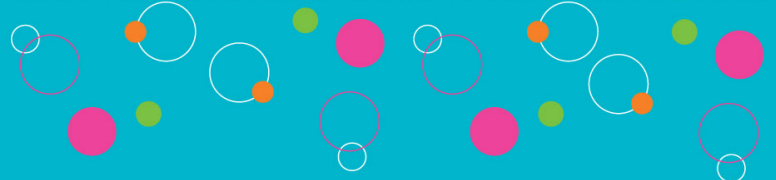
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 East Hanover, NJ 07936 www.tricoastaldesign.com. Made in China



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Total Nt. Wt. 0.6 oz / 17.5 g
 5 lip balms 0.12 oz / 3.5 g

SPRING WATER SPA™
ASSORTED LIP BALMS
 SPF 15

LIP BALM			
octinoxate oxybenzone dimethicone lipstick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-202-05	5 in 1 BOX		
1	NDC:49852-202-35	3.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2010	

Labeler - Tri-Coastal Design Company Inc. (609734900)**Establishment**

Name	Address	ID/FEI	Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture

Revised: 2/2010

Tri-Coastal Design Company Inc.