SHOPKO MOISTURE SPF 15 LIP BALM- oxybenzone, octinoxate, petrolatum stick Shopko

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

Octinoxate (7.5%), Oxybenzone (3.5%) Petrolatum (40.7%)

Purpose

Sunscreen, Sunscreen, Skin Protectant

Keep Out of Reach of Children

If swallowed get medical help or contact a Poison Control Center right away.

Uses

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned lips.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

Directions

Apply liberally before sun exposure and as needed. Children under 6 months of age: Ask a doctor before use.

Inactive Ingredients

Ozokerite, Mineral Oil, Isocetyl Stearate, Microcrystalline Wax, Isopropyl Lanolate, Lanolin, Copernicia Cerifera (Carnauba) Wax, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadenis Leaf Extract, Paraffin, Cetyl Alcohol, Tocerpheryl Linoleate, Flavor, Methylparaben, Propylparaben.

Package/Label Principal Display Panel





SHOPKO MOISTURE SPF 15 LIP BALM

oxybenzone, octinoxate, petrolatum stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-733
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	3.5 mg in 1 g	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40.7 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	17.13 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	16.75 mg in 1 g
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	3.50 mg in 1 g
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	3.00 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	1 mg in 1 g
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	.60 mg in 1 g

Product Characteristics		
Color	WHITE	Score
Shape		Size
Flavor		Imprint Code

Contains

P	acl	kag	ing

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC · 370 12 - 733 - 03 1 g in 1 CONTAINED			

Marketing Information

9			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/15/2013	

Labeler - Shopko (023252638)

Registrant - Shopko (023252638)

Establishment

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(37012-733), LABEL(37012-733)

Revised: 7/2013 Shopko