SHOPKO CHERRY SPF 4 LIP BALM- padimate o, 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

Padimate O, Petrolatum

Purpose

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

Mineral Oil, Ozokerite, Flavor, Microcrystalline Wax, Isopropyl Myristate, Phenyl Trimethicone, Copernicia Cerifera (Carnauba) Wax, Lanolin, Euphorbia Cerifera (Candelilla) Wax, Cetyl Alcohol, Camphor, Red 6 Lake (CI 15850), Methylparaben

Package/Label Principal Display Panel





SHOPKO CHERRY SPF 4 LIP BALM

padimate o, petrolatum stick

Product Information			
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:37012-731
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PETROLATUM (UNII: 4T6 H12BN9 U) (PETROLATUM - UNII:4T6 H12BN9 U)	PETROLATUM	44.0 mg in 1 g		
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	1.5 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
LIGHT MINERAL OIL (UNII: N6K5787QVP)	23.50 mg in 1 g		
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	3.00 mg in 1 g		
LANOLIN (UNII: 7EV65EAW6H)	1 mg in 1 g		
CERESIN (UNII: Q1LS2UJO3A)	17.50 mg in 1 g		
CARNAUBA WAX (UNII: R12CBM0EIZ)	1 mg in 1 g		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	2.23 mg in 1 g		

Product Characteristics			
Color	PINK	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-731-02	1 g in 1 CONTAINER		

Marketing Information			
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			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(37012-731), LABEL(37012-731)

Revised: 7/2013 Shopko