# WINCO CHERRY SPF 4 LIP BALM- padimate o, petrolatum stick Winco

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.

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#### **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

Do not use on damaged or broken skin

Stop use and ask a doctor: If rash or irritation develops and lasts for more than 7 days.

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. Reapply 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





## **WINCO CHERRY SPF 4 LIP BALM**

padimate o, petrolatum stick

Product Inform	- <b></b>
UPACHICT INTARM	NATION

HUMAN OTC DRUG NDC:67091-252 **Product Type Item Code (Source)** 

**TOPICAL Route of Administration** 

Active	Ingred	lient/	Active	M	oiet	y
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Ingredient Name	<b>Basis of Strength</b>	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	44.0 mg in 1 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	1.5 mg in 1 g

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mactive migredients				
Ingredient Name	Strength			
LIGHT MINERAL OIL (UNII: N6K5787QVP)	23.50 mg in 1 g			
MICROCRYSTALLINE 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: 0RE8K4LNJS)	2.23 mg in 1 g

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

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:67091-252- 30	1 g in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	01/02/2015		

## **Labeler -** Winco (056098817)

## Registrant - OraLabs (801824756)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(67091-252) , LABEL(67091-252)

Revised: 1/2022 Winco