

## **ORALABS CHAPICE CHERRY SPF 4 LIP BALM- padimate o, petrolatum stick**

**OraLabs**

*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

#### **Uses**

Helps prevent sunscreen

#### **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.

Keep out of reach of children: if swallowed get medical help or contact a Poison Control Center right away.

#### **Directions**

Apply liberally before sun exposure and as needed.

Children under the age of 6 months: Ask a doctor before use.

#### **Inactive ingredients**

Mineral oil, Ozokerite, Flavor, Microcrystalline Wax, Isopropyl Myristate, Phenyl Trimethicone, Copernicia Cerifera (Carnauba) Wax, Lanolin, Euphorbia Cerifera (Candellia) Wax, Cetyl Alcohol, Camphor, Red 6 Lake (C15850), Methylparaben

#### **Package/Label Principal Display Panel**

2.375in

SEALLED FOR YOUR PROTECTION  
Twist Cap To Break Seal

SEALLED FOR YOUR PROTECTION  
Twist Cap To Break Seal

**Drug Facts (Continued)**  
*Uses:* Helps prevent sunburn • Helps prevent and temporarily protect 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.  
**Keep out of reach of children:** If swallowed get medical help or contact a Poison Control Center right away.  
**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.  
**QUESTIONS? 1.800.290.0577**

**Drug Facts**

Active ingredients:	Purpose
Padimate-O (1.5 %)	Sunscreen
Petrolatum (44.0 %)	Skin Protectant

LAB-1001 LCS CHE YPIG 04

0 93000 01102 2

**Chap•Ice**  
 Lip Balm - SPF 4  
 CHERRY

**Chap•Ice**  
 Net Wt. 0.15 oz (4.25g)  
 ▼ Lift for Drug Facts Continued ▼

3.375in

**ORALABS CHAPICE CHERRY SPF 4 LIP BALM**

padimate o, petrolatum stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63645-111
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	15 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	440 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	235 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	175 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	30 mg in 1 g
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	18.5 mg in 1 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	22.3 mg in 1 g
CARNAUBA WAX (UNII: R12CBM0EIZ)	10 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	10 mg in 1 g
CANDELILLA WAX (UNII: WL0328HX19)	5 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	5 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	2 mg in 1 g
METHYLPARABEN (UNII: A2I8C7HI9T)	1 mg in 1 g
CHERRY (UNII: BUC5I9595W)	30 mg in 1 g
D&C RED NO. 6 (UNII: 481744AI4O)	12 mg in 1 g

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-111-01	4.25 g in 1 CYLINDER		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/03/2000	

**Labeler** - OraLabs (801824756)

**Registrant** - OraLabs (801824756)

**Establishment**

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-111)

Revised: 9/2012

OraLabs