# CHAPICE SPF 30 LIP BALM- octinoxate, octocrylene, oxybenzone, octisalate 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**

Octinoxate (7.5%), Octocrylene (10.0%), Oxybenzone (5.0%), Octisalate (5.0%)

#### **Purpose**

Sunscreen, Sunscreen, Sunscreen

#### Keep Out of Reach of Children

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

#### Uses

**Prevents Sunburns** 

#### 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, Petrolatum, Microcrystalline Wax, Ceresin, Flavor, Copernicia Cerifera (Carnauba) Wax, Caprylic/Capric Triglyceride, Titanium Dioxide (CI 77891), Stearic Acid, Tocopheryl Acetate, Aluminum Hydroxide.

## Package/Label Principal Display Panel





#### **CHAPICE SPF 30 LIP BALM**

octinoxate, octocrylene, oxybenzone, octisalate stick

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63645-163

**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** 5.0 mg in 1 g OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) **OCTOCRYLENE** 10.0 mg in 1 g OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) **OCTISALATE** 5.0 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
PETROLATUM (UNII: 4T6H12BN9U)	13.0 mg in 1 g	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	25.5 mg in 1 g	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.1 mg in 1 g	
CERESIN (UNII: Q1LS2UJO3A)	36 mg in 1 g	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	4 mg in 1 g	

Product	Characteristics
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Color WHITE Score

Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63645-163- 01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	10/09/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/09/2017	

# **Labeler -** OraLabs (801824756)

## Registrant - OraLabs (801824756)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-163) , LABEL(63645-163)

Revised: 11/2022 OraLabs