

## **ORALABS SPF 15 LIP BALM- avobenzene, octinoxate, 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**

Avobenzene (3.0%), Octinoxate (7.5%)

Petrolatum (42.3%)

#### **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. if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early aging caused by the sun. helps prevent and temporarily protects chafed, chapped or cracked lips. Helps prevent and protect from the drying effects of wind and cold weather

#### **Warnings**

For external use only: Do not use on damaged or broken skin. When using this product. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor: if rash occurs

#### **Directions**

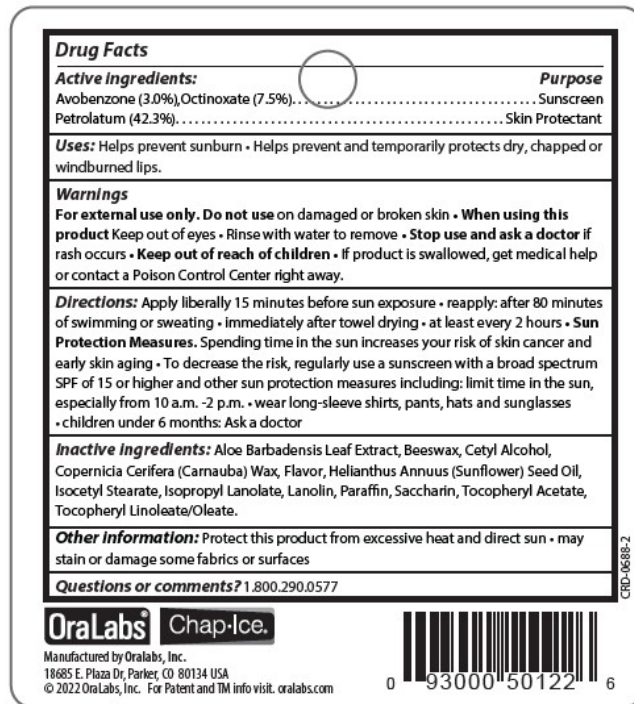
Apply liberally 15 minutes before sun exposure. Reapply: after 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours.

**SunProtectionMeasures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. to 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses. Children under 6 months: Ask a doctor.

#### **Inactive Ingredients**

Aloe Barbadensis Leaf Extract, Beeswax, Cetyl Alcohol, Copernicia Cerifera (Carnauba) Wax, Flavor, Helianthus Annuus (Sunflower) Seed Oil, Isocetyl Stearate, Isopropyl Lanolate, Lanolin, Paraffin, Saccharin, Tocopheryl Acetate, Tocopheryl Linoleate/Oleate.

## Package/Label Principal Display Panel



## ORALABS SPF 15 LIP BALM

avobenzone, octinoxate, petrolatum stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63645-181
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	423 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	230 mg in 1 g
<b>ISOCETYL STEARATE</b> (UNII: 3RJ7186O9W)	140 mg in 1 g
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	10 mg in 1 g

**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)

10 mg in 1 g

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-181-03	4.25 g in 1 CONTAINER; Type 0: Not a Combination Product	06/20/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/20/2022	

**Labeler** - OraLabs (801824756)

**Registrant** - OraLabs (801824756)

### Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-181) , LABEL(63645-181)

Revised: 9/2022

OraLabs