

**TEA TREE LIP BALM, SPF 15- octinoxate, oxybenzone 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.

Drug Facts

Active ingredient

Octinoxate (2.0%), Oxybenzone (4.5%)

Purpose

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

Synthetic Beeswax, Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Lanolin, Cocos Nucifera (Coconut) Oil, Flavor, Zea Mays (Corn) Oil, Tocopheryl Acetate, BHT, Melaleuca Alternifolia (Tea Tree) Leaf Oil

Package/Label Principal Display Panel

SAFETY SEALED FOR YOUR PROTECTION

Drug Facts (continued)

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 help prevent sunburn, not skin cancer or early skin aging. ■ **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 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 15 minutes before sun exposure ■ use a water resistant sunscreen if swimming or sweating ■ reapply at least every 2 hours ■ children under 6 months: ask a doctor

Other information ■ protect this product from excessive heat and direct sun ■ to report a suspected adverse reaction, contact Curad.

Inactive ingredients ■ beeswax, helianthus annuus (sunflower) seed oil, ricinus communis (castor)seed oil, lanolin, cocos nucifera (coconut) oil, flavor, zea mays (corn) oil, tocopheryl acetate, BHT, melaleuca alternifolia (tea tree) leaf oil

LAB-1451-2 LBXTTM NPIG 15

Drug Facts

Active ingredients	Purpose
Octinoxate 2.0%	Sunscreen
Oxybenzone 4.5%	Sunscreen

Use ■ helps protect against sunburn and chapped lips

TEA TREE LIP BALM, SPF 15

octinoxate, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-176
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	20 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	304 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	305 mg in 1 g
ACETYLATED LANOLIN (UNII: 2X654GD19H)	97 mg in 1 g

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-176-03	4 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(63645-176) , LABEL(63645-176)

Revised: 11/2022

OraLabs