SUNFROG ULTRA SPF 30 LIP BALM- octinoxate, octocrylene, oxybenzone, octisalate, petroleum jelly 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 (7.5%), Octocrylene (7.0%), Oxybenzone (5.0%), Octisalate (5.0%), Petrolatum (30.0%)

Purpose

Sunscreen, Sunscreen, Sunscreen, Sunscreen, Skin Protectant

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, Cetyl Alcohol, Mineral Oil, Paraffin, Polyethylene, Flavor, Caprylic/Capric Triglyceride, Titanium Dioxide (CI 77891), Stearic Acid, Aluminum Hydroxide, Lanolin, Phenyl Trimethicone, Oleyl Alcohol, Isopropyl Lanolate, Isopropyl Myristate, BHT, Tocopheryl Acetate, Propyl paraben, Aloe Barbadensis Leaf Extract, Methylparaben, Sodium Saccharin.

Package/Label Principal Display Panel

SUNFROG ULTRA SPF 30 LIP BALM

octinoxate, octocrylene, oxybenzone, octisalate, petroleum jelly stick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63645-165
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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5.0 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.0 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	7.0 mg in 1 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.1 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	16.8 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	7.0 mg in 1 g

METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 mg in 1 g

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor	VANILLA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-165-01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	11/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/29/2017	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-165) , LABEL(63645-165)

Revised: 11/2022 OraLabs