WINCO MOISTURE SPF 15 LIP BALM- oxybenzone, octinoxate, petrolatum stick Winco

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%), Oxybenzone (3.5%)

Petrolatum (40.7%)

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. Helps prevent and temporarily protects 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

Do not use on broken or damaged skin

Stop use and ask a doctor: If rash or irritation develops and lasts for more than 7 days.

When using this product keep out of eyes. Rinse with water to remove.

Directions

Apply liberally 15 minutes before sun exposure. Reapply as needed.

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

Inactive Ingredients

Ozokerite, Mineral Oil, Isocetyl Stearate, Microcrystalline Wax, Isopropyl Lanolate, Lanolin, Copernicia Cerifera (Carnauba) Wax, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadenis Leaf Extract, Paraffin, Cetyl Alcohol, Tocerpheryl Linoleate, Flavor, Methylparaben, Propylparaben.

Package/Label Principal Display Panel





WINCO MOISTURE SPF 15 LIP BALM

oxybenzone, octinoxate, petrolatum stick

Pro	duct	Inform	ation
	aace		GCIOII

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-250

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	3.5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40.7 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	17.13 mg in 1 g

LIGHT MINERAL OIL (UNII: N6K5787QVP) 16.75 mg in 1 g

ISOCETYL STEARATE (UNII: 3RJ7186O9W)	3.50 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	3.00 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	1 mg in 1 g
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.60 mg in 1 g

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 N 3		1 g in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/02/2015	

Labeler - Winco (056098817)

Registrant - OraLabs (801824756)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(67091-250) , LABEL(67091-250)

Revised: 1/2022 Winco