

WINCO ORIGINAL PETROLATUM- 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

Petrolatum, 45%

Purpose

Skin Protectant

Keep Out of Reach of Children

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

Uses

Helps prevent and temporarily protect dry, chapped or windburned lips.

Warnings

For external use only. Stop use and ask a doctor if rash or irritation develops and lasts. Children under 6 months of age: Ask a doctor before use.

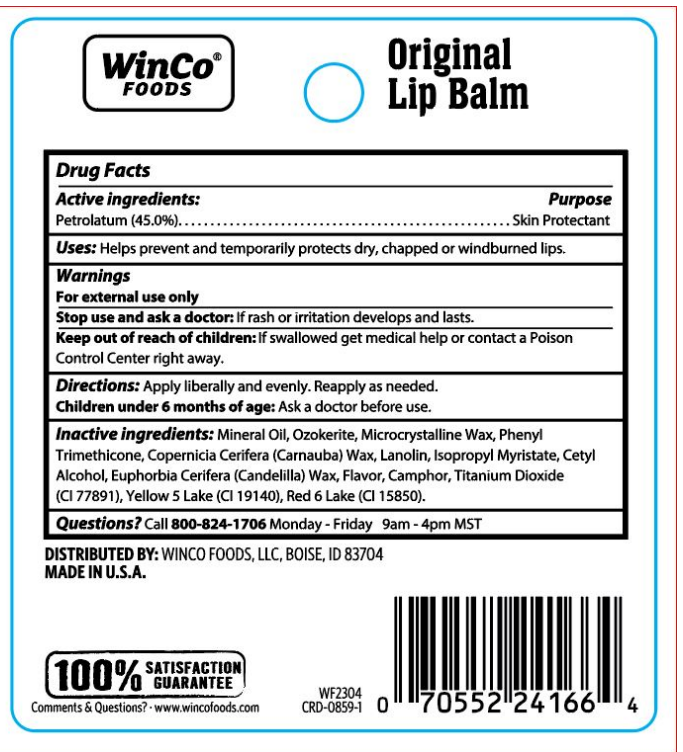
Directions

Apply as needed.

Inactive Ingredients

Camphor, Cetyl Alcohol, Copernicia Cerifera (Carnauba) Wax, Euphorbia Cerifera (Candelilla) Wax, Flavor, Isopropyl Myristate, Lanolin, Microcrystalline Wax, Mineral Oil, Ozokerite, Phenyl Trimethicone, Red 6 Lake (CI 15850), Titanium Dioxide (CI 77891), Yellow 5 Lake (CI 19140).

Package/Label Principal Display Panel



WINCO ORIGINAL PETROLATUM

petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	28 ug in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	17.5 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	3.0 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	1.0 mg in 1 g

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-253-01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	06/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/15/2023	

Labeler - Winco (056098817)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(67091-253) , LABEL(67091-253)

Revised: 6/2023

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