

AMISH ORIGINS SPF 15 LIP BALM- octinoxate, octocrylene, oxybenzone stick

Amish Origins

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 (2.0%), Oxybenzone (4.0%)

Purpose

Sunscreen, Sunscreen, 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.

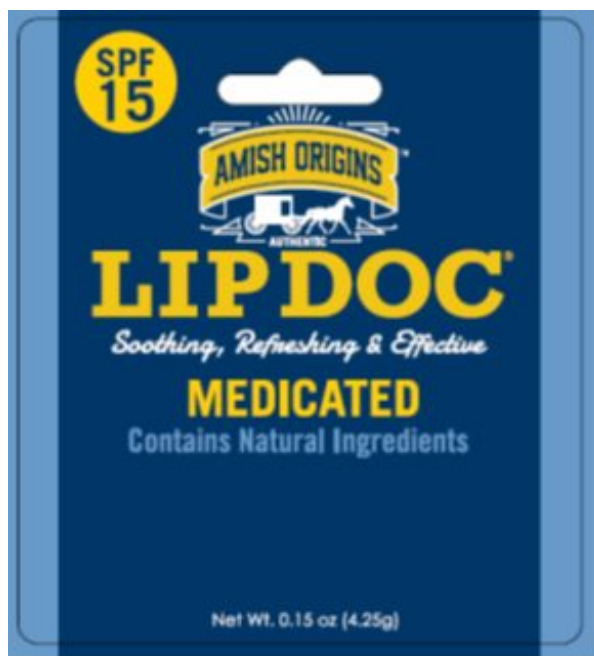
Directions

Apply liberally before sun exposure and as needed. Children under 6 months of age: Ask a doctor before use.

Inactive Ingredients

Petrolatum, Mineral Oil, Paraffin, Euphorbia Cerifera (Candelilla) Wax, Theobroma Cacao (Cocoa) Seed Butter, Menthol, Propylene Glycol, Eucalyptus Globulus (Eucalyptus) Oil, Abies Sibirica Oil, Methyl Salicylate, Cinnamomum Camphora (Camphor) Bark Oil, Isopropyl Myristate, Tocopheryl Acetate, Aloe Barbadenis Leaf Extract, Paraffin, Methylparaben.

Package/Label Principal Display Panel



AMISH ORIGINS SPF 15 LIP BALM

octinoxate, octocrylene, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62212-350
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: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	27.0 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	25.5 mg in 1 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	.29 mg in 1 g
CANDELILLA WAX (UNII: WL0328HX19)	8.0 mg in 1 g
MENTHOL, (+) - (UNII: C6B10E8P3W)	2.0 mg in 1 g

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62212-350-01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	08/17/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/17/2015	

Labeler - Amish Origins (079239259)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(62212-350) , LABEL(62212-350)

Revised: 4/2017

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