

USANA LIP MOISTURIZER- avobenzone, octinoxate, octisalate lipstick

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

Avobenzone 3.0%

Octinoxate 7.5%

Octisalate 5.0%

Purpose

Sunscreen

Keep Out of Reach of Children

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

Uses

Helps prevent sunburn. Help prevent and temporarily protect dry, chapped, or windburned lips if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

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.

Directions

Apply liberally before sun exposure and as needed.

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF or higher and other sun protection measures including: limiting time in the sun (especially from 10 a.m. - 2 p.m.) and wearing long-sleeve shirts, pants, hats, and sunglasses.

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

Inactive ingredients

Cocos Nucifera (Coconut) Oil, Beeswax, Ricinus Communis (Castor) Seed Oil, Flavor, Tocopherol, Butyrospermum Parki (Shea) Butter, Theobroma Cacao (Cocoa) Seed Butter

Package/Label Principal Display Panel

USANA LIP MOISTURIZER

avobenzene, octinoxate, octisalate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5.0 g

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	30 g
CASTOR OIL (UNII: D5340 Y2I9G)	23 g
WHITE WAX (UNII: 7G1J5DA97F)	27.5 g
COCOA BUTTER (UNII: 512O YT1CRR)	0.001 g

SHEA BUTTER (UNII: K49155WL9Y)	0.001 g
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	1.998 g
PEAR JUICE (UNII: F214DLA9BE)	2.0 g

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-128-02	1 in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/06/2012	

Labeler - Oralabs (801824756)

Registrant - Usana (804413250)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	LABEL(63645-128) , MANUFACTURE(63645-128)

Revised: 4/2012

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