PETROLEUM-FREE LIP BALM- octinoxate and oxybenzone lipstick Medline Industries, LP

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.

092 Curad Petroleum-Free Lip Balm

Active ingredients

Octinoxate 2.0%

Oxybenzone 4.5%

Purpose

Sunscreen

Sunscreen

Use

• helps protect against sunburn and chapped 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 help prevent sunburn, not skin cancer or early skin aging.
- 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 and lasts

Keep out of reach of children.

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

Directions

apply liberally 15 minutes before sun exposure

- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor

Other Information

- protect this product from excessive heat and direct sun
- to report a suspected adverse reaction, contact Curad.

Inactive ingredients

beeswax, BHT, cocos nucifera (coconut) oil, flavor, helianthus annuus (sunflower) seed oil, lanolin, melaleuca alternifolia (tea tree) leaf oil, ricinus communis (castor) seed oil, tocopheryl acetate, zea mays (corn) oil.

Manufacturing Information

Manufactured for: Medline Industries, LP Three Lakes Drive, Northfield, IL 60093 USA Made in USA of foreign and domestic materials www.curad.com 1-800-633-5463 REF: CUR0415 V1 RD220LB

Package Label



PETROLEUM-FREE LIP BALM octinoxate and oxybenzone lipstick						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5	3329-092	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Stren	ngth	Strength	

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 g
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4.5 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
YELLOW WAX (UNII: 2ZA36H0S2V)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
CASTOR OIL (UNII: D5340Y2I9G)			
LANOLIN (UNII: 7EV65EAW6H)			
COCONUT OIL (UNII: Q9L0073W7L)			
CORN OIL (UNII: 8470G57WFM)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
TEA TREE OIL (UNII: VIF565UC2G)			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53329- 092-83	1 in 1 BOX	04/01/2010	
1		4.2 g in 1 CONTAINER; Type 0: Not a Combination Product		
M	arketing	Information		

Category	Citation	Date	Date
OTC monograph final	M020	04/01/2010	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 8/2023

Medline Industries, LP