SUN XSPF 30 BROAD SPECTRUM SUNSCREEN LIP BALM- avobenzone, homosalate, octis alate, octocrylene, oxybenzone lipstick CoreTex Products, INC

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.

Sun X Lip Balm

Active Ingredients

Avobenzone...3.0%

Homosalate...7.5%

Octisalate...5.0%

Octocrylene...2.5%

Oxybenzone...6.0%

Purpose

Sunscreen

Uses

Helps prevent sunburn.

• For external use only

Do not use on damaged or broken skin.

Stop use and ask a doctor if

rash occurs

When using this product

• keep out of eyes. Rinse to remove.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: **Ask a doctor**

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 value of 15 or higher and other sun protection measures:

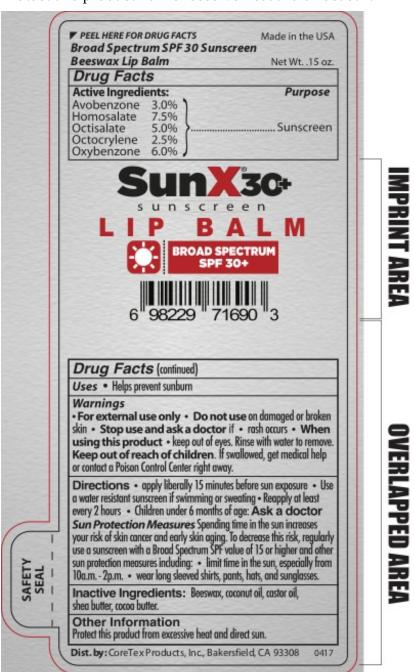
- limit time in the sun, especially from 10a.m.-2p.m.
- wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Beeswax, castor oil, cocoa butter, coconut oil, shea utter

Other Information

Protect this productfrom excessive heat and direct sun.



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avobenzone, homosalate, octisalate, octocrylene, oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.5 g in 100 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
COCONUT OIL (UNII: Q9L0O73W7L)			
WHITE WAX (UNII: 7G1J5DA97F)			
SHEA BUTTER (UNII: K49155WL9Y)			
COCOA BUTTER (UNII: 512OYT1CRR)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-105- 36	24 in 1 CONTAINER	0 1/0 1/20 17	
1		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:65753-105- 23	50 in 1 CONTAINER	0 1/0 1/20 17	
2		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:65753-105- 38	72 in 1 CONTAINER	0 1/0 1/20 17	
3		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 17	

Labeler - CoreTex Products, INC (061944620)

Establishment			
Name	Address	ID/FEI	Business Operations
CoreTex Products, INC		061944620	label(65753-105)

Establishment				
Name	Address	ID/FEI	Business Operations	
Raining Rose		083819404	manufacture(65753-105)	

Revised: 11/2019 CoreTex Products, INC