SUN X SPF 50 BROAD SPECTRUM SUNSCREEN LIP BALM- avobenzone, homosalate, octinoxate, octisalate, petrolatum lipstick CoreTex Products, INC

Sun X 50 Lip Balm 65753-108

Active Ingredients:

Avobenzone...3.0%

Homosalate...3.0%

Octinoxate.....7.5%

Octisalate.....5.0%

Petrolatum....40.0%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Skin Protectant

Uses

Helps protect against sunburn and chapped lips.

Warnings

Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

For external use only.

Stop use and ask a doctor

if rash or irritation develops and lasts.

Keep out of reach of children.

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

Directions:

Apply liberally before sun exposure and as needed.

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

Other information:

protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

C12-15 alkyl benzoate, caprylic/capric triglyceride, mineral oil, ozokerite, phenyl trimethicone, tocopherol

Questions?

1.877.684.5774

SunX 50 Lip Balm 65753-108



avobenzone, homosalate, octinoxate, octisalate, petrolatum lipstick

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65753-108

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40 g in 100 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	3 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
WHITE WAX (UNII: 7G1J5DA97F)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
COCONUT OIL (UNII: Q9L0O73W7L)			
PHENYL TRIMETHICONE (UNII: DROK5NOJ4R)			
TOCOPHEROL (UNII: R0ZB2556P8)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753- 108-36	24 in 1 CONTAINER	10/08/2021	
1		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:65753- 108-23	50 in 1 CONTAINER	10/08/2021	
2		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:65753- 108-38	72 in 1 CONTAINER	10/08/2021	
3		4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2017	

Labeler - CoreTex Products, INC (061944620)

Establishment				
Name	Address	ID/FEI	Business Operations	
CoreTex Products, INC		061944620	pack(65753-108)	

Establishment				
Name	Address	ID/FEI	Business Operations	
OraLabs, Inc.		801824756	manufacture(65753-108)	

Revised: 11/2023 CoreTex Products, INC