SUNSCREEN STICK- avobenzone, homosalate, octisalate, octocrylene stick Cosmuses Cosmetics (Ningbo) Co., Ltd.

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.

SPF30 sunblock stick

Drug facts

Active ingredient

Avobenzone 1.5%

Homosalate 4%

Octisalate 2%

Octocrylene 4%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- 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.

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

Directions

Apply liberally 15-20 minutes before sun exposure. Reapply as needed or after towel drying, swimming or perspiring. Children under 6 months of age: ask a doctor.

Other information:

Store at 20-25 °C (68-77 °F).

Inactive ingredients:

Paraffinum liquidum, Petrolatum, Ozokerite, Ethylhexyl Palmitate, beeswax, Microcrystalline Wax, Phenoxyethanol, Fragrance, BHT

30x52mm

Drug Facts SPF30 Sunscreen Stick

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Homosalate 4%	Sunscreen
Octisalate 2%	Sunscreen
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MADE IN CHINA 15a

SUNSCREEN STICK

avobenzone, homosalate, octisalate, octocrylene stick

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:82953-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
CERESIN (UNII: Q1LS2UJO3A)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
ETHYLHEXYL PALMITATE (UNII: 2865993309)			
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
PETROLATUM (UNII: 4T6H12BN9U)			
YELLOW WAX (UNII: 2ZA36H0S2V)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82953-006- 01	14 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022		
2	NDC:82953-006- 02	15 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022		
3	NDC:82953-006- 03	2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2022	

Labeler - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Registrant - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmuses Cosmetics (Ningbo) Co., Ltd.		725290934	manufacture(82953-006)