

**SUNSCREEN 01- avobenzone,homosalate,octocrylene,octisalate cream
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 SUNSCREEN LOTION

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 10%

Octocrylene 10%

Octisalate 5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreased the risk of skin cancer and early skin aging caused by 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 occurs.

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

Directions

- apply liberally 15minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediate after towel drying
 - at least every 2 hours

- Sun Protection Measures

Spending time 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 including:

- limit time in the sun, especially from 10a.m.- 2p.m.
- wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months

Ask a doctor

Inactive ingredients

Aqua, Glycerin, Isopropyl Myristate, Cetearyl Alcohol, Glyceryl Stearate, Ceteth-25, Beeswax, Phenoxyethanol, Fragrance, Methylparaben, Propylparaben, Disodium EDTA, BHT

Other information

Protect this product from excessive heat and direct sun

	32mm																											
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SUNSCREEN 01

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82953-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-25 (UNII: 5KLY4IOG20)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-002-01	10 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
2	NDC:82953-002-02	20 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
3	NDC:82953-002-03	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
4	NDC:82953-002-04	35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
5	NDC:82953-002-05	45 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
6	NDC:82953-002-06	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
7	NDC:82953-002-07	57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	
8	NDC:82953-002-08	1.5 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/26/2022	

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(82953-002)

Revised: 8/2023

Cosmuses Cosmetics (Ningbo) Co., Ltd.