

**SUNSCREEN 01- avobenzone, homosalate, octocrylene, octisalate spray
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 Sun screen spray

Drug Facts

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octocrylene 10%

octisalate 5%

Purpose

Sunscreen

Uses

- Help prevent sunburn

Warnings

Skin Cancer/ Skin Aging Alert: Spending time in the sun increase your risk of skin cancer and early skin aging. This product has been shown only to 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 occurs.

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

Directions

Apply generously & evenly before sun exposure. Reapply as needed or after towel drying,

swimming or sweating.

Ask doctor before using on children under 6 months.

Inactive ingredients

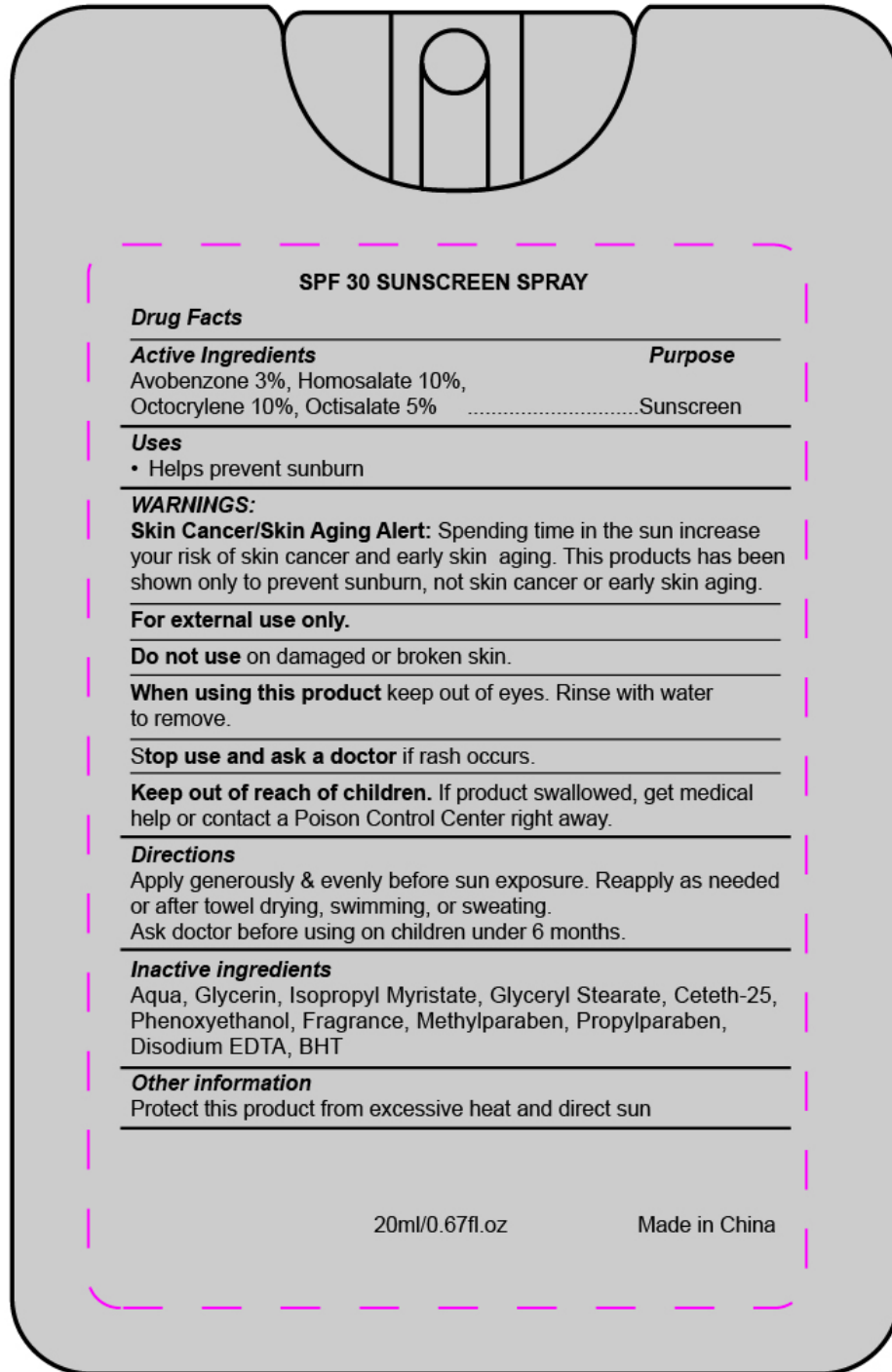
Aqua, Glycerin, Isopropyl Myristate, Glyceryl Stearate, Ceteth-25, phenoxyethanol, Fragrance, Methylparaben, Propylparaben, Disodium EDTA, BHT

Other information

Protect this product from excessive heat and direct sun.

SB107

45x66.7mm



SUNSCREEN 01

avobenzone, homosalate, octocrylene, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82953-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-003-01	10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	
2	NDC:82953-003-02	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	
3	NDC:82953-003-03	20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/30/2022	

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(82953-003)

Revised: 10/2022

Cosmuses Cosmetics (Ningbo) Co., Ltd.