

**SPF30 SUNSCREEN AND ANTIBACTERIAL HAND SANITIZER- alcohol, avobenzone, homosalate, octocrylene, octisalate**  
**Zhejiang Ayan Biotech Co., Ltd.**

-----  
**SPF30 Sunscreen Spray, & Antibacterial Hand Sanitizer**

***Drug Facts Antibacterial Hand Sanitizer***

***Active Ingredients***

Ethyl Alcohol 62%

***Purpose***

Antiseptic

***Uses***

•Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.

***WARNINGS:***

For external use only. Flammable. Keep away from fire or flame.

Do not apply around eyes,

***Do not use***

in ears & mouth.

***When using this product***

avoid contact with eyes. In case of contact flush eyes with water.

***Stop use and ask a doctor***

if redness or irritation develop and persist for more than 72 hours.

***Keep out of reach of children.***

Children must be supervised in use of this product.

***Directions***

Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry

***Inactive ingredients.***

water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, carbomer, fragrance.

***Other Information***

Store at room temperature 15°C to 30°C (59° F to 86° F)

***Questions?***

Call

***Drug Facts SPF30 Sunscreen Spray******Active Ingredients***

Avobenzone 3%, Homosalate 10%,  
Octocrylene 10%, Octisalate 5%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn

***WARNINGS:***

Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn skin cancer or early skin aging. This product is water resistant or sweat resistant. **Skin Cancer/Skin Aging Alert:NOTNOT**

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

### ***Directions***

Non-Water Resistant Product • Apply liberally 15 minutes before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months: Ask a doctor

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including: •Limit time in the sun, especially from 10 a.m. to 2 p.m. •Wear long sleeve shirts, pants, hats and sunglasses. **Sun Protection Measures.**

### ***Inactive ingredients.***

Water, Glycerin, Potassium Phosphate, VP/Hexadecene Copolymer, Dimethicone, Phenoxyethanol, Acrylates/Beheneth-25 Methacrylate Copolymer, Caprylyl Glycol, Bisabolol, Fragrance, Triethanolamine, Disodium EDTA

### ***Other information***

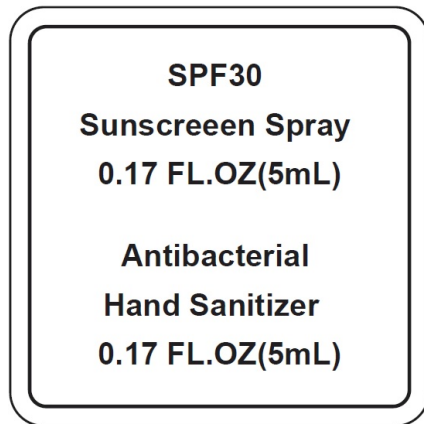
•Protect this product from excessive heat and direct sun

### ***Questions?***

Call

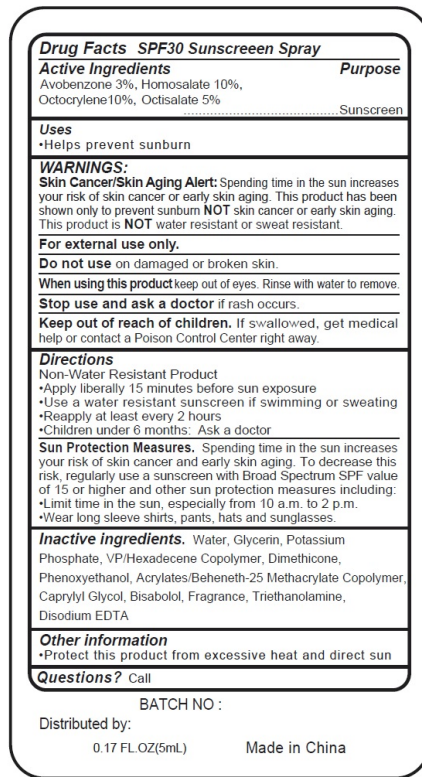
### **Package Labeling:**

25x25mm

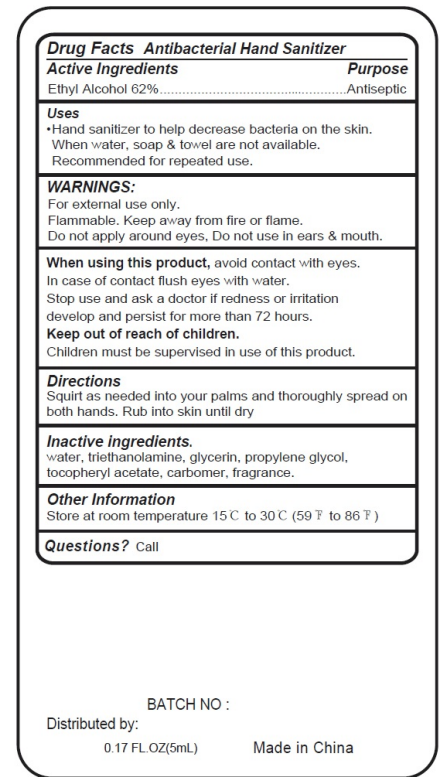


Front

25x46mm



25x46mm



Back

## SPF30 SUNSCREEN AND ANTIBACTERIAL HAND SANITIZER

alcohol, avobenzone, homosalate, octocrylene, octisalate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70412-817
---------------------	----------------	---------------------------	---------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-817-05	1 in 1 KIT	09/01/2018	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 BOTTLE	5 mL
<b>Part 2</b>	1 TUBE	5 mL

### Part 1 of 2

## ANTIBACTERIAL HAND SANITIZER

ethyl alcohol spray

## Product Information

**Item Code (Source)** NDC:70412-119

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-119-05	1 in 1 BOX		
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	09/01/2018	

## Part 2 of 2

### SPF30 SUNSCREEN

avobenzone, homosalate, octocrylene, ocitsalate spray

## Product Information

**Item Code (Source)** NDC:70412-238

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE	100 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)			OCTOCRYLENE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE	50 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>POTASSIUM PHOSPHATE, UNSPECIFIED FORM</b> (UNII: B7862WZ632)				
<b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)				
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)				
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)				
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)				
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)				
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)				
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-238-05	5 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	09/01/2018	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	09/01/2018	

**Labeler** - Zhejiang Ayan Biotech Co., Ltd. (544377996)

## Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ayan Biotech Co., Ltd.		544377996	manufacture(70412-817, 70412-119, 70412-238)

