

HAND SANITIZER- alcohol gel
Zhejiang Ayan Biotech 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.

Hand Sanitizer

Drug facts

Active ingredients

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

For Hand Sanitizing

Warnings

For external use only-hands.

Flammable.Keep away from heat and flame.

When using this product

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- Avoid contact with broken skin.
- Do not inhale or ingest.

Stop use and ask a doctor

- if skin irritation or develops.

Keep out of reach of children.

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

Directions

- Wet hands thoroughly with product and allow to dry without wiping.
- For children under 6 use only under adult Supervision
- Not recommender for infants

Other information

- Do not store above 105°F.
- May discolor some fabrics.
- Harmful to wood finishes and plastics.

Inactive ingredients

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Package Labeling:



Drug Facts

Hand Sanitizer
473ml/16 fl.oz.

Active ingredients.....	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Uses: For Hand Sanitizing

Warnings: For external use only-hands.

Flammable.Keep away from heat and flame.

When using this product • Keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Avoid contact with broken skin. • Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children.

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

Directions:Wet hands thoroughly with product and allow to dry without wiping • For children under 6 use only under adult Supervision. • Not recommended for infants.

Other information:Do not store above 105°F. • May discolor some fabrics. • Harmful to wood finishes and plastics.

Inactive ingredients:

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Distributed by: Newacme LLC 2808 Vail Ave
Commerce, CA, 90040

MADE IN CHINA

Package Labeling: 15ml



Drug Facts

Hand Sanitizer
0.5 fl oz (15ml)

Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Use For hand washing to decrease bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame.

For External Use Only

When using this product avoid contact with eyes. If contact occurs rinse eyes thoroughly with water.

Stop use and ask a doctor if skin irritation or rash develops and continues for more than 72 hours.

Keep out reach of children. If swallowed get medical help or contact your Poison Control Center right away.

Directions

- Place a palmful (5 grams) of product in one hand.
- Spread on both hands and rub into skin until dry (approximately 1 to 2 minutes).

Other information

- Do not store above 105°F. • May discolor some fabrics.
- Harmful to wood finishes and plastics.

Inactive ingredients

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water

Distributed by: Newacme LLC
Commerce, CA, 90040

2808 Vail Ave
Made in China

Package Labeling: 53ml



Drug Facts	Hand Sanitizer
Active ingredients	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic
Use For hand washing to decrease bacteria on the skin.	
Directions ■ Spread on both hands.	
Other Information ■ store at 20° C (68° to 77° F). ■ may discolor fabrics.	
Warnings	
For external use only.	
Flammable. Keep away from fire or flame.	
Do not apply around eyes.	
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 & persist for more than 72 hrs.	
Keep out of reach of children. Children must be supervised in use of this product.	
Inactive Ingredients Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.	
Distributed by: Newacme LLC 2808 Vail Ave Commerce, CA, 90040 MADE IN CHINA	

Package Labeling: 60ml



Drug Facts

Hand Sanitizer

60mL/2 fl.oz.

Active ingredients.....**Purpose**
Ethyl Alcohol 70% v/v Antiseptic

Uses: For Hand Sanitizing

Warnings: For external use only-hands,

Flammable.Keep away from heat and flame.

When using this product • Keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Avoid contact with broken skin. • Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children.

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

Directions:Wet hands thoroughly with product and allow to dry without wiping • For children under 6 use only under adult supervision. • Not recommended for infants.

Other information:Do not store above 105°F. • May discolor some fabrics. • Harmful to wood finishes and plastics.

Inactive ingredients:

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Distributed by: Newacme LLC 2808 Vail Ave
Commerce, CA, 90040

MADE IN CHINA

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 412-194
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q16 7V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9 E8 X80 D2L0)	

TROLAMINE (UNII: 9O3K93S3TK)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-194-73	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
2	NDC:70412-194-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
3	NDC:70412-194-53	53 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
4	NDC:70412-194-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ayan Biotech Co.,Ltd.		544377996	manufacture(70412-194)

Revised: 5/2020

Zhejiang Ayan Biotech Co.,Ltd.