# HAND SANITIZER- alcohol gel

# Newacme llc

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.

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#### **Hand Sanitizer**

# **Drug Facts**

# Active ingredient

Ethyl Alcohol 70% v/v

# **Purpose**

Antiseptic

#### Use

For hand washing to decrease bacteria ont he 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 of reach of children.

If swallowed get medical help or contact your Poison Control 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

# Package Labeling: 15 ml



# **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: 53 ml



Package Labeling: 60 ml

# **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: 473 ml

# **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

Kills 99.99% of Germs

**Soothing Gel** 



16 fl oz (473mL)

# **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

#### HAND SANITIZER

alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74341-194

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)ALCOHOL0.7 mL in 1 mL

#### **Inactive Ingredients**

WATER (UNII: 059QF0KO0R)

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging						
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:74341-194-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020			
2	NDC:74341-194-53	53 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020			
3	NDC:74341-194-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020			
4	NDC:74341-194-73	473 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 - Newacme llc (117465743)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Zhejiang Ayan Biotech Co.,Ltd.		544377996	manufacture(74341-194)		

Revised: 5/2020 Newacme llc