

**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 Ingredients**

Ethyl Alcohol 62%

**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 or ask a doctor**

if skin irritation 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 a 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.

**Package Labeling: 74341-191-08**

	<p><b>Drug Facts</b> <span style="float: right;">Hand Sanitizer 236ml/8 fl.oz.</span></p> <table border="1"> <tr> <td><b>Active ingredients</b>.....</td> <td><b>Purpose</b></td> </tr> <tr> <td>Ethyl Alcohol 62%</td> <td>Antiseptic</td> </tr> </table> <p><b>Uses:</b> For Hand Sanitizing</p> <p><b>Warnings:</b> For external use only-hands.</p> <p><b>Flammable:</b> Keep away from heat and flame.</p> <p><b>When using this product</b> • Keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Avoid contact with broken skin. • Do not inhale or ingest.</p> <p><b>Stop use and ask a doctor</b> if skin irritation develops.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or call a Poison Control Center right away.</p> <p><b>Directions:</b> Wet hands thoroughly with product and allow to dry without wiping • For children under 6 use only under adult Supervision. • Not recommended for infants.</p> <p><b>Other information:</b> Do not store above 105°F. • May discolor some fabrics. • Harmful to wood finishes and plastics.</p> <p><b>Inactive ingredients:</b> Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.</p> <p>Distributed by: Newacme LLC 2808 Vail Ave Commerce, CA, 90040 NDC-7041211236 MADE IN CHINA</p>	<b>Active ingredients</b> .....	<b>Purpose</b>	Ethyl Alcohol 62%	Antiseptic
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**Package Labeling: 74341-191-16**

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# HAND SANITIZER

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74341-191
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C00X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74341-191-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74341-191-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333E	04/01/2020	

**Labeler** - Newacme LLC (117465743)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zhejiang Ayan Biotech Co.,Ltd.		544377996	manufacture(74341-191)

