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.

Hand Sanitizer

Drug Facts

Active ingredients

Ethyl Alcohol 70% v/v

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 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.

Package Labeling:1000ml



Package Labeling:2000ml



Sanitizer

Kills 99.99% of Germs

Soothing Gel



68 fl oz (2000ml)

Drug Facts

Hand Sanitizer 2000ml/68 fl.oz.

Active ingredients.....Purpose
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Warnings: For external use only-hands.

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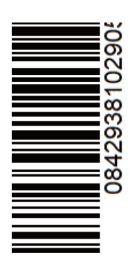
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Distributed by: Newacme LLC 2808 Vail Ave
Commerce, CA, 90040 MADE IN CHINA



Package Labeling:3.780ml



HAND SANITIZER

alcohol gel

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:74341-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:74341-004-12	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020		
2 NDC:74341-004-13	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020		
3 NDC:74341-004-14	$3780\ mL$ 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	Business Operations		
SHANDISHI Biological Technology Co., Ltd.		411868994	manufacture(74341-004)		

Revised: 7/2020 Newacme LLC