

ANTIMICROBIAL HAND- alcohol gel

Calego International Inc.

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.

Antimicrobial Hand Gel

Drug Facts

Active ingredient

Ethyl Alcohol 70% w/w

Purpose

Antimicrobial

Use

hand sanitizer to help reduce microbes on the skin

Warnings

Flammable. Keep away from fire or flame

For external use only.

When using this product,

do not use in or near the eyes. If contact occurs, rinse thoroughly with water

Stop use and ask a doctor

if irritation and redness develops and persists for more than 72 hours and continues

Keep out of reach of children.

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

Directions

- put enough gel in your palm to cover hands and rub hands together rapidly until dry
- children under 6 years of age should be supervised when using this product

Other information

- store below 110 °F (43 °C)
- may discolor certain fabrics or surfaces

Inactive ingredients

carbomer, fragrance, glycerin, propylene glycol, silicone, triethanolamine, water (aqua)

Package Labeling:



Face



Back

60 ml

ANTIMICROBIAL HAND

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72487-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72487-008-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - Calego International Inc. (081320445)

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