

HAND SANITIZER- alcohol gel
Innovent 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.

Germisept Hand Sanitizer 70% 60 mL

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information





- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, Carbomer, purified water USP, aminomethyl propanol, propylene glycol

Package Label - Principal Display Panel



GERMisept [®] 70% ALCOHOL HAND SANITIZER	
Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Uses •to decrease bacteria on the skin that could cause disease •recommended for repeated use.	
Warnings	
•For external use only •Flammable •Keep away from fire or 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 •irritation or redness develops •condition persists for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions •Place enough product on hands to cover all surfaces. Rub hands together until dry. •Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information • Do not store above 105 °F • May discolor some fabrics • Harmful to wood finishes and plastics.	
Inactive ingredients Aminomethyl propanol, Carbomer, Glycerin, Purified water, Propylene glycol.	
Distributed by:    Innovent Inc., Newport Beach, CA 92660, USA. Visit us at: www.germisept.com Manufactured in China	
	

60 mL NDC: 70335-302-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70335-302	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	42 mL in 60 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		0.3 mL in 60 mL		
CARBOMER 934 (UNII: Z135WT9208)		0.18 mL in 60 mL		
WATER (UNII: 059QF0K00R)		17.1 mL in 60 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		0.12 mL in 60 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		0.3 mL in 60 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70335-302-01	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/12/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/12/2020		

Labeler - Innovent Inc. (079973489)

Registrant - Innovent Inc. (079973489)

Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG JINGHUI COSMETICS SHARE CO., LTD		529558167	manufacture(70335-302)

Revised: 6/2020

Innovent Inc.