

## **GERMS ARE STUPID- alcohol gel Germs, 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.*

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### **70 No Scent Gel**

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) (70%, 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.
- e. Carbomer

### **Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

For hand washing to decrease bacteria on the skin - Recommended for repeated use.

### **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 occurs. These may be signs of a serious condition.

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

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.

### **Directions**

Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision.

### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics. Harmful to wood finishes and plastics

### **Inactive ingredients**

glycerin, carbomer, and purified water USP

### **Package Label - Principal Display Panel**

**Drug Facts**

**Active Ingredient(s):**  
Ethyl Alcohol 70%.....Antiseptic, Disinfectant

**Uses:** For hand washing to decrease bacteria; recommended for repeated use.

**Warnings:** For external use only. Flammable from heat and flame.

**Directions:** Children less than 2 years old: Do not use on open wounds.

**When Using This Product:** Keep out of eyes and mouth. In case of contact with eyes, rinse with water. Stop use and ask a doctor if irritation. These may be signs of a serious condition. Keep out of children. If swallowed, get medical help in contact with Poison Control Center immediately.

**Directions:** Wet hands thoroughly with product to dry without wiping. For children under six, use only under supervision.

**Inactive Ingredient(s):** Purified water, or glycerin.

**Other Information:** Store between 15-25 degrees and excessive heat above 40C (104F) some fabrics. Harmful to wood finishes and plastic.

**Visit Us Online:** Visit us online at [www.germstestupid.com](http://www.germstestupid.com)

GERMS ARE STUPID!

HAND SANITIZER TODAY!

70% ALCOHOL

8 50021 633

1440F - USA

## GERMS ARE STUPID

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81821-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81821-001-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Germs, Inc. (118017927)

**Registrant** - Southern Chem Industries LLC (056025778)

## Establishment

Name	Address	ID/FEI	Business Operations
Southern Chem Industries LLC		056025778	manufacture(81821-001)

Revised: 4/2021

Germs, Inc.