# 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.

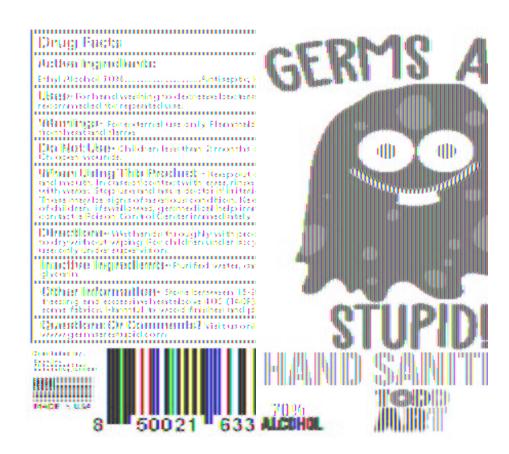
#### Other information

- 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



# **GERMS ARE STUPID**

alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81821-001

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M)

70 mL in 100 mL

# Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) 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		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								
Na me	Address	ID/FEI	<b>Business Operations</b>					
Southern Chem Industries LLC		056025778	manufacture(81821-001)					

Revised: 4/2021 Germs, Inc.