

## **GUARD HAND SANITIZING GEL- alcohol gel**

### **Guard Products 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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### **Guard Hand Sanitizing 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) (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 80% 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.

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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, hydrogen peroxide, purified water USP

<p><b>WATERLESS HAND CLEANSER</b> is a hand sanitizing gel including &gt;70% v/v Ethyl Alcohol &amp; carefully selected emollients such as Vitamin E &amp; Aloe Vera moisturizers.</p> <p><b>HAZARD STATEMENTS</b> May cause eye irritation. May be harmful if swallowed.</p> <p><b>PRECAUTIONARY STATEMENTS</b> Forms smooth, slippery surfaces on floors, posing an accident risk.</p> <p><b>STORAGE AND HANDLING</b> Store in a dry and well-ventilated place. Store in a closed container. Keep cool. Use / follow appropriate industrial practice.</p> <p><b>SPILL RESPONSE</b> Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.</p> <p><b>SHIPPING DESCRIPTION</b> ORM-D, Consumer Commodity, in accordance with 49CFR (HMR 181), 173.150 and 173.156. Ethyl alcohol solutions, 3, UN1170, PG II</p> <p> THE SPECIALTY CHEMICAL SOLUTION <b>DISTRIBUTED BY:</b> Guard Products, Inc. PO Box 1498 Bethel Island, CA 94511 510-635-4353 guardproducts.com</p> <p><b>Consult SDS for Full Statements of Health, Safety, &amp; Environmental Information</b></p>	 <p><b>hand sanitizing gel</b></p> <p><b>&gt;70% V/V ETHYL ALCOHOL</b></p> <p><b>HAND SANITIZING GEL</b></p> <p>LIGHTLY SCENTED &amp; INFUSED WITH <b>VITAMIN E &amp; ALOE VERA</b></p> <ul style="list-style-type: none"> <li>✓ PARABEN FREE</li> <li>✓ SULFATE FREE</li> <li>✓ MADE IN THE USA</li> </ul> <p>WORKS WITH MOST AUTOMATED DISPENSING SYSTEMS</p> <p><b>3785 mL (1 US GALLON - 128 US FL OZ)</b></p>	<p><b>DRUG FACTS</b></p> <table border="1"> <thead> <tr> <th>ACTIVE INGREDIENT</th> <th>PURPOSE</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol &gt; 70% v/v</td> <td>Antimicrobial</td> </tr> </tbody> </table> <p><b>USES</b> To help keep hands clean. For repeated use.</p> <p><b>WARNINGS</b> <u>Flammable. Keep away from fire or flame.</u> For external use only. When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears or persists. Keep out of reach of children. If swallowed, get medical help or contact Poison Control immediately.</p> <p><b>DIRECTIONS</b> •Apply enough product to your palm to completely wet / cover both hands. •Rub hands together briskly for up to 30 seconds or until dry, covering all surfaces.</p> <p><b>INACTIVE INGREDIENTS</b> Purified Water (Aqua)   Glycerith-26   PEG-40 Hydrogenated Castor Oil   Carbomer   Vitamin E Acetate   Aloe Vera   Fragrance</p> <p><b>OTHER INFORMATION</b> •Store below 110°F (43°C) •May discolor certain fabrics or surfaces</p> <p><b>GUARD PRODUCTS</b> THE SPECIALTY CHEMICAL SOLUTION ©2020 Guard Products Inc. ALL RIGHTS RESERVED <u>Transportation / Spill 24 - Hour Emergency Phone Number:</u> <b>1-800-424-9300 / +1 703-527-3887</b></p>	ACTIVE INGREDIENT	PURPOSE	Ethyl Alcohol > 70% v/v	Antimicrobial
ACTIVE INGREDIENT	PURPOSE					
Ethyl Alcohol > 70% v/v	Antimicrobial					

3.875 L NDC: 77668-002-01

## GUARD HAND SANITIZING GEL

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77668-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.42 L in 100 L
WATER (UNII: 059QF0K00R)	27.61 L in 100 L
PEG-40 HYDROGENATED LANOLIN (UNII: 959P5CXE48)	0.3 L in 100 L
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.01 L in 100 L
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.5 L in 100 L
ALOE VERA FLOWER (UNII: 575DY8C1ER)	0.01 L in 100 L
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.15 L in 100 L

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77668-003-01	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

**Labeler** - Guard Products Inc (116830285)**Registrant** - Custom Blenders (057505117)**Establishment**

Name	Address	ID/FEI	Business Operations
custom blenders		057505117	manufacture(77668-003)

Revised: 6/2020

Guard Products Inc