

## **GUARD HAND SANITIZER- alcohol liquid**

### **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 Sanitizer**

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.

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**

- 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

3.875 L NDC: 77668-001-0

<p><b>WATERLESS HAND SANITIZER</b> is an 80% v/v Ethyl Alcohol Antiseptic Solution.</p>	 <p><b>Guard Products</b> THE SPECIALTY CHEMICAL SOLUTION</p> <p><b>ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION</b></p> <p><b>Hand Sanitizer</b></p> <p><b>NON-STERILE SOLUTION</b></p> <ul style="list-style-type: none"> <li>✓ PARABEN FREE</li> <li>✓ GLUTEN FREE</li> <li>✓ SULFATE FREE</li> <li>✓ MADE IN THE USA</li> </ul>	<p><b>DRUG FACTS</b></p>				
<p><b>HAZARD STATEMENTS</b> May cause eye irritation. May be harmful if swallowed.</p>		<table border="1"> <thead> <tr> <th>ACTIVE INGREDIENT</th> <th>PURPOSE</th> </tr> </thead> <tbody> <tr> <td>Alcohol 80% v/v.....</td> <td>Antiseptic</td> </tr> </tbody> </table>	ACTIVE INGREDIENT	PURPOSE	Alcohol 80% v/v.....	Antiseptic
ACTIVE INGREDIENT		PURPOSE				
Alcohol 80% v/v.....		Antiseptic				
<p><b>PRECAUTIONARY STATEMENTS</b> Forms smooth, slippery surfaces on floors, posing an accident risk.</p>		<p><b>USE(S)</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.</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>WARNINGS</b> <u>Flammable. Keep away from fire or flame.</u> For external use only. Do not use in children less than 2 months of age or on open skin wounds. When using this product, keep out of eyes, ears and mouth. In case of contact, 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 Poison Control Center right away.</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>DIRECTIONS</b></p> <ul style="list-style-type: none"> <li>•Place enough product on hands to cover all surfaces then rub hands together until dry.</li> <li>•Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>					
<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><b>INACTIVE INGREDIENTS</b> Glycerin, hydrogen peroxide, purified water USP</p>					
 <p>THE SPECIALTY CHEMICAL SOLUTION</p> <p><b>DISTRIBUTED BY:</b> Guard Products, Inc. PO Box 1498 Bethel Island, CA 94511 510-635-4353 guardproducts.com</p>	<p><b>OTHER INFORMATION</b></p> <ul style="list-style-type: none"> <li>•Store between 15-30C (59-86F) and avoid freezing and excessive heat above 40C (104F).</li> </ul>					
<p>Consult SDS for Full Statements of Health, Safety, &amp; Environmental Information</p>	<p><b>GUARD PRODUCTS</b> THE SPECIALTY CHEMICAL SOLUTION</p> <p>©2020 Guard Products Inc. ALL RIGHTS RESERVED</p>					
<p>Transportation / Spill 24 – Hour Emergency Phone Number: 1-800-424-9300 / +1 703-527-3887</p>						

208.175 L NDC: 77668-001-55

<b>WATERLESS HAND SANITIZER</b> is an 80% v/v Ethyl Alcohol Antiseptic Solution.
<b>HAZARD STATEMENTS</b> May cause eye irritation. May be harmful if swallowed.
<b>PRECAUTIONARY STATEMENTS</b> Forms smooth, slippery surfaces on floors, posing an accident risk.
<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.
<b>SPILL RESPONSE</b> Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.
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**waterless hand sanitizer**



**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION**

## Hand Sanitizer

**NON-STERILE SOLUTION**

- ✓ PARABEN FREE
- ✓ GLUTEN FREE
- ✓ SULFATE FREE
- ✓ MADE IN THE USA

**208,175 mL (55 US GALLONS – 7,040 US FL OZ)**

<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENT</b>	<b>PURPOSE</b>
Alcohol 80% v/v	Antiseptic
<b>USE(S)</b>	
Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
<b>WARNINGS</b>	
<u>Flammable. Keep away from fire or flame.</u>	
For external use only. Do not use in children less than 2 months of age or on open skin wounds.	
When using this product, keep out of eyes, ears and mouth. In case of contact, 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 Poison Control Center right away.	
<b>DIRECTIONS</b>	
•Place enough product on hands to cover all surfaces then rub hands together until dry.	
•Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>INACTIVE INGREDIENTS</b>	
Glycerin, hydrogen peroxide, purified water USP	
<b>OTHER INFORMATION</b>	
•Store between 15-30C (59-86F) and avoid freezing and excessive heat above 40C (104F).	
<b>GUARD PRODUCTS</b>	
THE SPECIALTY CHEMICAL SOLUTION	
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1041 L NDC: 77668-001-99

<b>WATERLESS HAND SANITIZER</b> is an 80% v/v Ethyl Alcohol Antiseptic Solution.	 <p><b>Guard Products</b> THE SPECIALTY CHEMICAL SOLUTION</p> <p><b>ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION</b></p> <h1>Hand Sanitizer</h1> <p><b>NON-STERILE SOLUTION</b></p> <ul style="list-style-type: none"> <li>✓ PARABEN FREE</li> <li>✓ GLUTEN FREE</li> <li>✓ SULFATE FREE</li> <li>✓ MADE IN THE USA</li> </ul> <p><b>NET CONTENTS: 275 US GALLONS</b></p>	<b>DRUG FACTS</b>
<b>HAZARD STATEMENTS</b> May cause eye irritation. May be harmful if swallowed.		<b>ACTIVE INGREDIENT</b> <span style="float: right;"><b>PURPOSE</b></span> Alcohol 80% v/v <span style="float: right;">Antiseptic</span>
<b>PRECAUTIONARY STATEMENTS</b> Forms smooth, slippery surfaces on floors, posing an accident risk.		<b>USE(S)</b> Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.
<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.		<b>WARNINGS</b> <u>Flammable. Keep away from fire or flame.</u> <b>For external use only. Do not use in children less than 2 months of age or on open skin wounds.</b> When using this product, keep out of eyes, ears and mouth. In case of contact, 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 Poison Control Center right away.
<b>SPILL RESPONSE</b> Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.		<b>DIRECTIONS</b> •Place enough product on hands to cover all surfaces then rub hands together until dry. •Supervise children under 6 years of age when using this product to avoid swallowing.
<b>SHIPPING DESCRIPTION</b> UN1987, Alcohols, n.o.s., 3, PG II. Can be shipped ORM-D, Consumer Commodity, via ground freight in accordance with 49CFR (HMR 181), 173.150 and 173.156.		<b>INACTIVE INGREDIENTS</b> Glycerin, hydrogen peroxide, purified water USP
 <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>	<b>OTHER INFORMATION</b> •Store between 15-30C (59-86F) and avoid freezing and excessive heat above 40C (104F).	
Consult SDS for Full Statements of Health, Safety, & Environmental Information	<p style="text-align: center;"><b>GUARD PRODUCTS</b> THE SPECIALTY CHEMICAL SOLUTION</p>	
Transportation / Spill 24 – Hour Emergency Phone Number: <b>1-800-424-9300 / +1 703-527-3887</b>	<p style="text-align: center;">©2020 Guard Products Inc. ALL RIGHTS RESERVED</p>	

GUARD HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77668-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L	
Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L		
WATER (UNII: 059QF0K00R)	18.425 L in 100 L		
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77668-001-55	208.175 L in 1 DRUM; Type 0: Not a Combination Product	05/20/2020	
2	NDC:77668-001-99	1041 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/20/2020	
3	NDC:77668-001-01	3.875 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(77668-001)

Revised: 4/2020

Guard Products Inc