

## **HAND SANITIZER GEL- hand sanitizer gel gel**

### **Total Beverage Services**

*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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### **Guide Energy 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.

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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

## Package Label - Principal Display Panel



<b>CUSTOMER:</b>	<b>DATE:</b>	<b>PROOF #:</b>	<b>INKS:</b>	<b>COPY POSITION:</b>
Total Beverage Services	27-MAY-20	01	K 300 CLEAR MATERIAL dieline	
<b>JOB NAME:</b>	<b>DIMENSIONS:</b>	<b>QUANTITY:</b>	<b>SUBSTRATE:</b>	
12oz Guide Gel	3 x 4.875	40,000	2.0 Mil Opticlear+Laminate	
<b>JOB NOTES:</b>		Please check and verify all aspects of this proof and these technical specifications. With your approval you are assuming responsibility for the content, design, and specifications of the label(s) shown. If you cannot adequately proofread or verify all aspects of this proof, a hard copy will be mailed to you. Changes or revisions may delay the printing process accordingly and may result in additional art and/or proof charges. This proof is intended to be a representation of the final product. If a contract color proof is required, please call your Customer Service Representative. Please fax this signed approval to (405) 682-1650.		
		<input type="checkbox"/> Ok as is. Please print. By: _____ Date: _____		

354.88 ml NDC 77042-780-12

## HAND SANITIZER GEL

hand sanitizer gel gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78387-780
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
MONOETHANOLAMINE (UNII: 5KV86114PT)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78387-780-12	354.88 mL in 1 BOTTLE; 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** - Total Beverage Services (927976477)

Establishment			
Name	Address	ID/FEI	Business Operations
Guide Energy Solutions		117045830	manufacture(78387-780)

Establishment			
Name	Address	ID/FEI	Business Operations
Total Beverage Services		927976477	pack(78387-780) , label(78387-780)

Revised: 10/2020

Total Beverage Services