

## **HAND SANITIZER- alcohol liquid**

### **Integrated Green Force, LLC**

*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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### **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

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

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COMMERCIAL CLEANING PRODUCTS



# Hand Sanitizer

Non-sterile Solution

**Kills 99.9% of  
Germs & Bacteria**

**Alcohol Antiseptic 80%  
Topical Solution**

**NET CONTENT  
128 FL OZ / 1 Gallon / 3.7 Liters**

#### Drug facts

Active Ingredients  
Alcohol 80% v/v

#### Uses:

Hand Sanitizer is used to  
cause disease.  
For use when soap and water

#### Directions:

Fill in the Sanitizer  
Spray/Place enough  
Rub hands together  
Supervise children  
product to avoid water

#### Other information:

- Store between 45°F - 75°F
- Avoid freezing and thawing

#### Inactive ingredients:

Glycerin, Hydroxyethyl

#### Manufactured by:

Intergreen  
Green  
4611 Green  
Kansas, MO  
Tel: 417-421-2100



7835 mL NDC: 78311-090-01

**Drug facts**

Active Ingredients	Purpose
Alcohol 80% v/v .....	Antiseptic

**Uses:**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.  
For use when soap and water are not available.

**Directions:**

Fill in the Sanitizer in a spraying bottle.  
Spray/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.

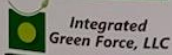
**Other information:**

- Store between 15°C - 30°C (59°F - 86°F).
- Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients:**

Glycerin, Hydrogen Peroxide, Purified Water USP.

Manufactured by:



**Integrated  
Green Force, LLC**  
4611 Green Bay Rd, Ste 2  
Kenosha, WI 53144 USA  
Tel: 414-369-2643



**Made in USA**  
[www.bmastercleaner.com](http://www.bmastercleaner.com)

# HAND SANITIZER

alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78311-090
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78311-090-01	1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/15/2020	

**Labeler** - Integrated Green Force, LLC (037106115)

**Registrant** - Integrated Green Force, LLC (037106115)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Integrated Green Force, LLC		037106115	manufacture(78311-090)

Revised: 1/2023

Integrated Green Force, LLC