

**HAND SANITIZER- alcohol liquid**  
**InkJet, 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.*

-----

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**



**INKJET, INC.**  
**HAND SANITIZER**

**INGREDIENTS:**  
 95% ETHANOL, 0.5% HYDROXYL METHYL UREA, HYDROXYETHYL UREA

**PRECAUTIONS:**  
 Avoid contact with eyes. If contact occurs, flush with water for at least 15 minutes. If irritation occurs, discontinue use and consult a physician.

**SAFETY:**  
 Use for disinfection purposes only.

**PROPERTIES:**  
 Non-toxic, non-corrosive, non-flammable, non-oxidizing, non-volatile, non-hazardous to the environment.

**FLAMMABLE PRODUCT:**

**SAFETY DATA SHEET (SDS) REFERENCE:**  
 E00406034 v1

**PRODUCTION DATE:** 09/09/20

**VOLUME:** 3 gal

**HAZARD PICTOGRAMS:**

**Flammable (F+):** A red diamond with a flame icon, indicating a highly flammable liquid or solid.

**Irritant (Xi):** A red diamond with an exclamation mark icon, indicating a liquid or solid that causes irritation to the skin or eyes.







**Drug Facts**

<b>Active Ingredient(s)</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. <b>Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b> * in children less than 2 months of age * on open skin wounds	
<b>When using this product</b> 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 Poison Control Center right away.	
<b>Directions</b> * Place enough product on hand to cover all surfaces. Rub hands together until dry. * Supervise children under 6 years of age when using this product to avoid swallowing	
<b>Other information</b> * Store between 15-30C(59-86F) * Avoid freezing and excessive heat above 40C(104F)	
<b>Inactive ingredients</b> hydrogen peroxide, purified water, glycerin USP	



Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

Net Quantity: 1 US Gallon (128 fl. oz.)  
Batch# C2720

**UN1987**  
Alcohols, n.o.s., (Ethanol)



Alcohol Antiseptic 80%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution

Net Quantity: 1 US Quart  
Batch# C2720

**UN1987**  
Alcohols, n.o.s., (Ethanol)

...  
...  
... can cause disease.  
...  
... from heat or flame.  
... and mouth. In case of  
... These may be  
... medical help or contact  
... Rub hands together  
... this product to avoid  
...  
... glycerin USP



000 mL NDC: 00000-000-00

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77386-903
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	



## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77386-903-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77386-903-04	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77386-903-05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77386-903-06	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77386-903-07	1022060 mL in 1 CONTAINER; 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** - InkJet, Inc. (609299839)

## Establishment

Name	Address	ID/FEI	Business Operations
InkJet, Inc.		609299839	manufacture(77386-903)

Revised: 4/2020

InkJet, Inc.