

## **HAND SANITIZER- alcohol spray**

### **PrintJet Corp**

*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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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 75% 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, Fragrance

### Package Label - Principal Display Panel

3785 ml NDC: 76795-738-17

<p><b>Drug Facts</b></p> <hr/> <p><b>Active ingredient[s]</b> Alcohol 75%</p> <hr/> <p><b>Purpose:</b> Antiseptic</p> <hr/> <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> <hr/> <p><b>Warning</b> For external use only. Flammable. Keep away from heat or flame</p> <hr/> <p><b>Do not use</b> • on children less than 2 months of age • on open skin wounds</p> <hr/> <p><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <hr/> <p><b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.</p> <hr/> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	 <p>The label features a blue cross logo with the text "ALL WAYS TO HEALTH" in the center. Below the logo, it reads "Hand Sanitizer Spray" in large blue letters, followed by "Alcohol Antiseptic" and "Kills 99.9% of Germs*" in smaller blue text. The volume "1 Gallon (3.78L)" is prominently displayed in the middle. At the bottom, it specifies "75% Topical Solution", "Made in the USA", and "Non-sterile Solution". The background of the label is a light blue gradient with a water droplet graphic.</p>	<p><b>Directions</b></p> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul> <hr/> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>• Store between: 15-30C (59-86F)</li><li>• Avoid freezing &amp; excessive heat above 40C (104F)</li></ul> <hr/> <p><b>Inactive ingredients</b> glycerin, hydrogen peroxide, DI water, fragrance.</p> <hr/> <p><b>Produced By</b> PrintJet Corp. www.printjet.net p. 888-375-5680 7816 Burden Road Machesney Park, IL 61115</p> <hr/> <p><b>Emergency Call</b></p> <p>1-800-255-3924      7679573717 Int'l 1-813-248-0585</p>
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946 ml NDC: 76795-738-16

<b>Drug Facts</b>
<b>Active ingredient:</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> • on children < 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.
<b>Stop use &amp; ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.

  
**Hand Sanitizer Spray**  
**Alcohol Antiseptic**  
**Kills 99.9% of Germs**

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**32 oz. (.95L)**  
  
**75% Topical Solution**  
**Made in the USA**  
**Non-sterile Solution**

- 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 & excessive heat above 40C (104F)

**Inactive ingredients**  
glycerin, hydrogen peroxide, DI water, fragrance.

**Produced By:**  
PrintJet Corp.  
7816 Burden Road  
Machesney Park, IL 61115  
815-877-7511 f. 815-877-7621  
www.printjet.net

**Emergency Call**  
1-800-255-3924  
Int'l 1-813-248-0585 7679573716

473 ml NDC: 76795-738-15

<b>Drug Facts</b>
<b>Active ingredient:</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> • on children < 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.
<b>Stop use &amp; ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.

  
**Hand Sanitizer Spray**  
**Alcohol Antiseptic**  
**Kills 99.9% of Germs**

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**16 oz. (475ml)**  
  
**75% Topical Solution**  
**Made in the USA**  
**Non-sterile Solution**

- 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 & excessive heat above 40C (104F)

**Inactive ingredients**  
glycerin, hydrogen peroxide, DI water, fragrance.

**Produced By:**  
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7816 Burden Road  
Machesney Park, IL 61115  
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www.printjet.net

**Emergency Call**  
1-800-255-3924  
Int'l 1-813-248-0585 7679573715

237 ml NDC: 76795-738-14



<b>Drug Facts</b>
<b>Active ingredient[s]</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may potentially cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> • on 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.
<b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> 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 & excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, DI water, fragrance.

### Produced By

PrintJet Corp.  
www.printjet.net p. 888-375-5680  
7816 Burden Road  
Machesney Park, IL 61115

### Emergency Call

1-800-255-3924  
Int'l 1-813-248-0585

7679573714

177 ml NDC: 76795-738-13

<b>Drug Facts</b>
<b>Active ingredient[s]</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may potentially cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> on 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.
<b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> 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 & excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, DI water, fragrance.

### Produced By

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www.printjet.net p. 888-375-5680  
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Machesney Park, IL 61115

### Emergency Call

1-800-255-3924  
Int'l 1-813-248-0585

7679573713

118 ml NDC: 76795-737-12

<b>Drug Facts</b>
<b>Active ingredient[s]</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may potentially cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use*</b> on 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.
<b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.

  
**Hand Sanitizer Spray**  
**Alcohol Antiseptic**  
 Kills 99.9% of Germs\*  
  
**75% Topical Solution**  
**4 oz. (118ml)**  
**Made in the USA**  
**Non-sterile Solution**

<b>Directions</b>
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>
<b>Other information</b>
<ul style="list-style-type: none"> <li>Store between: 15-30C (59-86F)</li> <li>Avoid freezing &amp; excessive heat above 40C (104F)</li> </ul>
<b>Inactive ingredients</b>
glycerin, hydrogen peroxide, DI water, fragrance.
<b>Produced By</b>
PrintJet Corp. www.printjet.net p. 888-375-5680 7816 Burden Road Machesney Park, IL 61115
<b>Emergency Call</b>
1-800-255-3924 Int'l 1-813-248-0585
7679573712

60 ml NDC: 76795-738-11

<b>Drug Facts</b>
<b>Active ingredient[s]</b> Alcohol 75%
<b>Purpose:</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that may potentially cause disease. For use when soap and water are not available.
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> <ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul>
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
<b>Stop use and ask a doctor</b> If irritation or rash occurs. These may be Drug Facts signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.

  
**Hand Sanitizer Spray**  
**Alcohol Antiseptic**  
 75% Topical Solution  
  
**2 oz. (60ml)**  
**Made in the USA**  
**Non-Sterile Solution**

<b>Directions</b>
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>
<b>Other information</b>
<ul style="list-style-type: none"> <li>Store between: 15-30C (59-86F)</li> <li>Avoid freezing &amp; excessive heat above 40C (104F)</li> </ul>
<b>Inactive ingredients</b>
glycerin, hydrogen peroxide, DI water, fragrance.
<b>Produced By</b>
PrintJet Corp. www.printjet.net p. 888-375-5680 7816 Burden Road Machesney Park, IL 61115
<b>Emergency Call</b>
1-800-255-3924 Int'l 1-813-248-0585
7679573711

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76795-738
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75.725 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	7.5 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.75 mL in 100 mL
WATER (UNII: 059QF0KO0R)	16 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.025 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76795-738-11	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
2	NDC:76795-738-12	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
3	NDC:76795-738-13	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
4	NDC:76795-738-14	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
5	NDC:76795-738-15	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
6	NDC:76795-738-16	946 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	
7	NDC:76795-738-17	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/26/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/26/2020	

**Labeler** - PrintJet Corp (158605449)

**Registrant** - Sue L Sotelo (158605449)

## Establishment

Name	Address	ID/FEI	Business Operations
PrintJet Corp		158605449	manufacture(76795-738)

Revised: 4/2020

PrintJet Corp