

UNIQUE HAND SANITIZER- alcohol hand sanitizer gel
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.

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

473 mL NDC: 76795-742-07

<table border="1"><tr><td>Drug Facts</td></tr><tr><td>Active ingredient: Alcohol 70%</td></tr><tr><td>Purpose: Antiseptic</td></tr><tr><td>Use[s] Hand sanitizer to help reduce bacteria that may cause disease. For use when soap and water are not available.</td></tr><tr><td>Warning For external use only. Flammable. Keep away from heat or flame</td></tr><tr><td>Do not use<ul style="list-style-type: none">• on children < 2 months of age• on open skin wounds</td></tr><tr><td>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td>Stop use & ask a doctor If irritation or rash occurs. These may be Drug Facts signs of a serious condition.</td></tr><tr><td>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</td></tr></table>	Drug Facts	Active ingredient: Alcohol 70%	Purpose: Antiseptic	Use[s] Hand sanitizer to help reduce bacteria that may cause disease. For use when soap and water are not available.	Warning For external use only. Flammable. Keep away from heat or flame	Do not use <ul style="list-style-type: none">• on children < 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 & ask a doctor If irritation or rash occurs. These may be Drug Facts signs of a serious condition.	Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.		<table border="1"><tr><td>Directions<ul style="list-style-type: none">• 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.</td></tr><tr><td>Other information<ul style="list-style-type: none">• Store between: 15-30C (59-86F)• Avoid freezing & excessive heat above 40C (104F)</td></tr><tr><td>Inactive ingredients glycerin, hydrogen peroxide, DI water, hydroxypropylcellulose</td></tr><tr><td>Distributed By: Unique Products 3860 Commerce Dr. St. Charles, IL 60174 630-762-8800 www.cleaning-supplies.com</td></tr><tr><td>Emergency Call 1-800-255-3924 7679574205 Int'l 1-813-248-0585</td></tr></table>	Directions <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Store between: 15-30C (59-86F)• Avoid freezing & excessive heat above 40C (104F)	Inactive ingredients glycerin, hydrogen peroxide, DI water, hydroxypropylcellulose	Distributed By: Unique Products 3860 Commerce Dr. St. Charles, IL 60174 630-762-8800 www.cleaning-supplies.com	Emergency Call 1-800-255-3924 7679574205 Int'l 1-813-248-0585
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3785 mL NDC: 76795-742-05

Drug Facts	 <p>UNIQUE PRODUCTS</p> <p>Hand Sanitizer Gel</p> <p>Alcohol Antiseptic</p> <p>Kills 99.9% of Germs</p> <p>1 Gallon (3.78L)</p> <p>70% Topical Solution</p> <p>Made in the USA</p> <p>Non-sterile Solution</p>	Directions <ul style="list-style-type: none"> 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.
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UNIQUE HAND SANITIZER

alcohol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76795-742
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.35 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.15 mL in 100 mL
WATER (UNII: 059QF0K00R)	27.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76795-742-05	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

2	NDC:76795-742-07	3785 mL in 1 BOTTLE, PLASTIC; 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 - PRINTJET CORP (158605449)

Registrant - SUE SOTELO (158605449)

Establishment			
Name	Address	ID/FEI	Business Operations
PRINTJET CORP		158605449	manufacture(76795-742)

Revised: 7/2020

PRINTJET CORP