

HAND SANITIZER- alcohol gel
One Up Manufacturing 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.

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 70% 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, propylene glycol, carbopol ETD 2020, purified water USP, 85% Triethanolamine

Package Label - Principal Display Panel

30 mL NDC: 75518-221-02

Drug Facts	
Active Ingredient(s) Ethanol 70%.....	PurposeAntiseptic
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For when soap and water are not available.	
Danger: Highly Flammable, keep away from fire and flame. Causes serious eye irritation.	
When using this product ■Keep out of eyes ■If in eyes, rinse cautiously with water for several minutes ■Remove contact lenses, if present and easy to do, continue rinsing ■In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish ■Avoid contact with broken skin ■Do not inhale or ingest	
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Directions ■Wet hands thoroughly with product and allow to dry without wiping. ■For children under 6, use only under adult supervision. ■Not recommended for infants.	
Other information ■Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. ■May discolor some fabrics. ■Harmful to wood finishes and plastics. ■No smoking. ■Keep container tightly closed.	
Inactive ingredients: Water, Glycerin, Propylene Glycol, Carbopol® ETD 2020, Triethanolamine	



FRAGRANCE FREE

30ML
(1.00 FL. OZ)

Use biocides safely. Always read the label and product information before use. Store in a well-ventilated place. Keep cool. Eye protection not required normally but wear eye protection where there is a risk of this product getting in the eyes.

LIQUID REIGN LLC.
GARDENA, CA 90248

The complex block contains the product's branding and safety information. At the top, it says "FRAGRANCE FREE". Below that is a red rounded rectangle containing the text "30ML" in large white letters and "(1.00 FL. OZ)" in smaller white letters below it. Underneath the volume information is a paragraph of safety instructions. Below the instructions is the manufacturer's name and address: "LIQUID REIGN LLC. GARDENA, CA 90248". At the bottom of this section are two diamond-shaped warning symbols: one with an exclamation mark and one with a flame. The entire complex block is set against a light gray background.

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MD
ESSENTIAL LIQUIDS

HAND SANITIZER

SANITIZING GEL FRAGRANCE FREE

30ML
(1.00 FL. OZ)



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ONE UP MANUFACTURING
GARDENA, CA 90248

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50 mL NDC: 75518-221-03

<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active Ingredient(s)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethanol 70%.....</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For when soap and water are not available.</td> </tr> <tr> <td colspan="2">Danger: Highly Flammable, keep away from fire and flame. Causes serious eye irritation.</td> </tr> <tr> <td colspan="2">When using this product ■Keep out of eyes ■If in eyes, rinse cautiously with water for several minutes ■Remove contact lenses, if present and easy to do, continue rinsing ■In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish ■Avoid contact with broken skin ■Do not inhale or ingest</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away, 1 (800) 222-1222.</td> </tr> <tr> <td colspan="2">Directions ■Wet hands thoroughly with product and allow to dry without wiping. ■For children under 6, use only under adult supervision. ■Not recommended for infants.</td> </tr> <tr> <td colspan="2">Other information ■Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. ■May discolor some fabrics. ■Harmful to wood finishes and plastics. ■No smoking. ■Keep container tightly closed.</td> </tr> <tr> <td colspan="2">Inactive ingredients: Water, Glycerin, Propylene Glycol, Carbopol® ETD 2020, Triethanolmine</td> </tr> </tbody> </table>	Drug Facts		Active Ingredient(s)	Purpose	Ethanol 70%.....	Antiseptic	Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For when soap and water are not available.		Danger: Highly Flammable, keep away from fire and flame. Causes serious eye irritation.		When using this product ■Keep out of eyes ■If in eyes, rinse cautiously with water for several minutes ■Remove contact lenses, if present and easy to do, continue rinsing ■In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish ■Avoid contact with broken skin ■Do not inhale or ingest		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, 1 (800) 222-1222.		Directions ■Wet hands thoroughly with product and allow to dry without wiping. ■For children under 6, use only under adult supervision. ■Not recommended for infants.		Other information ■Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. ■May discolor some fabrics. ■Harmful to wood finishes and plastics. ■No smoking. ■Keep container tightly closed.		Inactive ingredients: Water, Glycerin, Propylene Glycol, Carbopol® ETD 2020, Triethanolmine		<div style="font-size: 2em; font-weight: bold; color: blue;">HAND SANITIZER GEL</div> <div style="font-size: 4em; font-weight: bold; color: red; margin-top: 10px;">LIBERTY</div> <div style="font-weight: bold; color: white; background-color: blue; padding: 5px; display: inline-block;">MADE IN USA</div>	<p style="text-align: center; font-weight: bold; color: black;">FRAGRANCE FREE</p> <div style="text-align: center; background-color: red; color: white; padding: 10px; margin: 10px auto; width: 80%;"> 50ML (1.67 FL. OZ) </div> <p style="text-align: center;">Use biocides safely. Always read the label and product information before use. Store in a well-ventilated place. Keep cool. Eye protection not required normally but wear eye protection where there is a risk of this product getting in the eyes.</p> <p style="text-align: center; font-weight: bold; color: black;">LIQUID REIGN LLC. GARDENA, CA 90248</p> <div style="text-align: center; margin-top: 10px;"> </div>
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ESSENTIAL LIQUIDS

HAND SANITIZER

SANITIZING GEL

FRAGRANCE FREE

50ML
(1.67 FL. OZ)



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60 mL NDC: 75518-221-04

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Active Ingredient(s)	Purpose
Ethanol 70%.....	Antiseptic
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HAND SANITIZER GEL

LIBERTY



MADE IN USA

FRAGRANCE FREE

60ML
(2.0 FL. OZ)

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LIQUID REIGN LLC.
GARDENA, CA 90248



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HAND SANITIZER

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100 mL NDC: 75518-221-05

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FRAGRANCE FREE

100ML
(3.33 FL. OZ)

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GARDENA, CA 90248



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120 mL NDC: 75518-221-06

Drug Facts	
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FRAGRANCE FREE

120ML
(4.00 FL. OZ)

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LIQUID REIGN LLC.
GARDENA, CA 90248



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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75518-221
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)	1.45 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75518-221-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75518-221-03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
3	NDC:75518-221-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
4	NDC:75518-221-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
5	NDC:75518-221-06	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/20/2020	

Labeler - One Up Manufacturing LLC (081038006)