# LIQUID HAND SANITIZER- alcohol liquid Outline Industries 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.

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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.

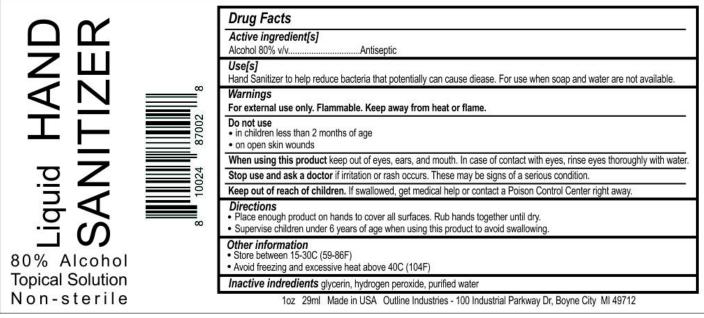
### Other information

- 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



29 mL NDC: 76613-001-29

LIQUID HAND SANITIZ alcohol liquid	ER							
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:76613-001(NDC:74914-001)				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			Basis	of Strength	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL		80 mL in 100 mL			

	Strongth							
	Strength							
GLYCERIN (UNII: PDC6A3C0OX)				1.45 mL in 100 mL				
HYDRO GEN PERO XID	0.125 mL in 100 mL							
WATER (UNII: 059QF0KO0R)								
Packaging								
0 0	Package Description	Marketing	g Start Date	Marketing End Dat				
# Item Code	<b>Package Description</b> 29 mL in 1 BOTTLE; Type 0: Not a Combination Produc		g Start Date	Marketing End Dat				
# Item Code	<b>č</b>		g Start Date	Marketing End Dat				
# Item Code	<b>č</b>		g Start Date	Marketing End Dat				
# Item Code   1 NDC:76613-001-29	29 mL in 1 BOTTLE; Type 0: Not a Combination Produc		g Start Date	Marketing End Dat				
# Item Code	29 mL in 1 BOTTLE; Type 0: Not a Combination Produc	t 04/23/2020	g Start Date g Start Date	Marketing End Dat				

# Labeler - Outline Industries LLC (009847814)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Outline Industries LLC		009847814	repack(76613-001)

Revised: 4/2020

Outline Industries LLC