# HAND SANITIZER- alcohol solution Gilchrist & Soames

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.

-----

#### G&S Instant Hand Sanitizer 16oz 473mL

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.

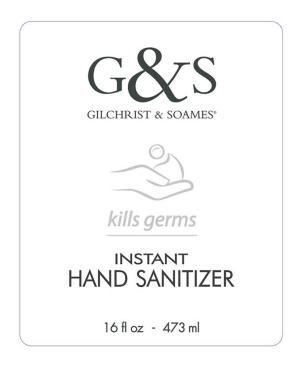
### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

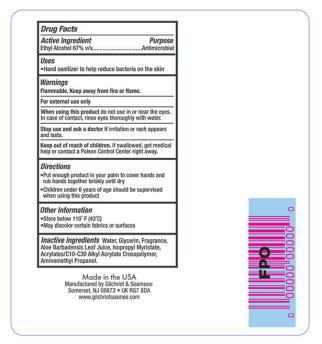
glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel



#### **FRONT PANEL**





### Actual Bar Code# 840008801359

#### **BACK PANEL**



## 473 mL NDC:64596-388-16

## HAND SANITIZER alcohol solution **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:64596-388 TOPICAL **Route of Administration Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 67 mL in 100 mL **Inactive Ingredients**

Ingredient Name	Strength			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
WATER (UNII: 059QF0KO0R)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				

	Marketing Start Marketing End
# Item Code Package Description	Date Date
1 NDC:64596-388- 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Product	09/08/2020

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	09/08/2020				

## Labeler - Gilchrist & Soames (052683856)

## Registrant - Gilchrist & Soames (052683856)

Establishment			
Name	Address	ID/FEI	Business Operations
Gilchrist & Soames		052683856	manufacture(64596-388)

Revised: 9/2020 Gilchrist & Soames