# 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.

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#### G&S Instant Hand Sanitizer 1.25oz 37mL

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.

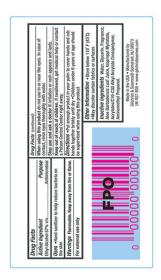
#### Other information

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

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

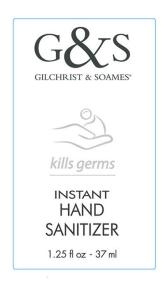
## Package Label - Principal Display Panel



Actual Bar Code# 840008801335

#### **BACK PANEL**





## **FRONT PANEL**

CHCHDICT	PROJECT: Gilchrist & Soames Hand Sanitizer			d Sanitizer	PART NO: G&S Formulation
GILCHRIST & SOAMES*	Product: 1,25 floz Hand Sanitizer Label				INK COLORS: CMYK SPOT
Somerset, NJ 08873 UK RG7 8DA	Product Details: White Opaque Wrap Around Label. PMS 446 and PMS Cool Gray 3 Print. Bottle: Thann Bottle.				PMS 446 PMS cool Gray 3
www.gilchristsoames.com	Date: 9/1/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR	White Opaque Label
REVISION 1: Revised Drug Facts Panel Date: 9/1/2020				PLEASE NOTE: The colors used on this proof are solely intended to furnish the best quality representation of our finished product. The colors used are photographic and bear no relationship to the inks used in the finished product.	
REVISION 2:	Date:			ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES	
REVISION 3: Date:			Approval Signature: Date:		

## 37 mL NDC:64596-388-12

HAND SANITIZER				
alcohol solution				
<b>Product Information</b>				
Product Type	HUMAN OTC DRUG	CC DRUG Item Code (Source) NI		NDC:64596-388
Route of Administration	TOPICAL			
Active Ingredient/Active Moi	ety			
Ingredient Name			Basis of Strengtl	h Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	67 mL in 100 mL
Inactive Ingredients				
Ingredient Name				
ISOPROPYL MYRISTATE (UNII: 0 RE	BK4LNJS)			
CARBOMER INTERPOLYMER TYPE	<b>A (55000 CPS)</b> (UNII: 59TL3W	G5CO)		

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
AMINO METHYLPRO PANOL (UNII: LU49 E6626Q)	

Packaging				
# Item Co	le Package Description	Marketing Start Date	Marketing End Date	
1 NDC:64596-3	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combina Product	tion 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