# INSTANT HAND SANITIZER- hand sanitizer 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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#### BAC 30 oz

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**

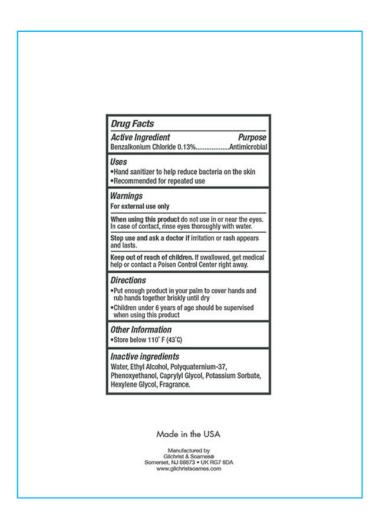
glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel** 



# **FRONT PANEL**

OH OHD ICT	PROJECT: Gilchrist & Soames Hand Sanitizer				PART NO: BKC Version
GILCHRIST & SOAMES*	Product: 30 fl oz 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: 30 oz Bottle				PMS 446 PMS Cool Gray 3
www.gilchristsoames.com	Date: 4/15/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR	White Opaque Label
REVISION 1: Revised Drug Facts Date: 4/7/2020				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: Revised INCI to Remove Translations for Aqua & Parfum Date: 4/15/2020				ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES	
REVISION 3:				Date:	Approval Signature: Date:



## **BACK PANEL**



887 mL NDC: 64596-222-88

# INSTANT HAND SANITIZER hand sanitizer solution Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64596-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients					
Ingredient Name	Strength				
WATER (UNII: 059QF0KO0R)	93.33 mL in 100 mL				
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	0.23 g in 100 mL				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.08 g in 100 mL				
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	0.02 g in 100 mL				
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.26 g in 100 mL				
POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)	0.8 g in 100 mL				
ALCOHOL (UNII: 3K9958V90M)	5 g in 100 mL				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:64596-222- 88	887 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/30/2020			

# Labeler - Gilchrist & Soames (052683856)

# Registrant - Gilchrist & Soames (052683856)

Establishment					
Name	Address	ID/FEI	Business Operations		
Gilchrist & Soames		052683856	manufacture(64596-222)		

Revised: 4/2020 Gilchrist & Soames