

## **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 mL**

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

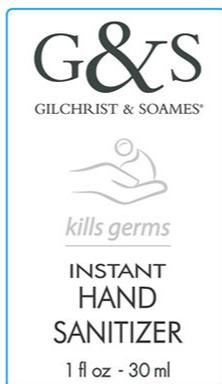
glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

<b>Drug Facts</b>	
<b>Active Ingredient</b> Benzalkonium Chloride 0.13%	<b>Purpose</b> Antimicrobial
<b>Uses</b> • Hand sanitizer to help reduce bacteria on the skin • Recommended for repeated use	
<b>Warnings</b> For external use only When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Put enough product in your palm to cover hands and rub hands together briskly until dry • Children under 6 years of age should be supervised when using this product	
<b>Other Information</b> • Store below 110° F (43° C)	
<b>Inactive Ingredients</b> Water, Ethyl Alcohol, Polyquaternium-37, Phenoxyethanol, Caprylyl Glycol, Potassium Sorbate, Methylparaben, Fragrance.	
Made in the USA Manufactured by Gilchrist & Soames® Somerset, NJ 08873 • UK RG7 8DA www.gilchristsoames.com	

## BACK PANEL

 <p>Somerset, NJ 08873 UK RG7 8DA</p> <p>www.gilchristsoames.com</p>	PROJECT: <b>Gilchrist &amp; Soames Hand Sanitizer</b>		PART NO: <b>BKC Version</b>	
	Product: 1 floz Hand Sanitizer Label		INK COLORS: <input type="checkbox"/> CMYK <input checked="" type="checkbox"/> SPOT	
	Product Details: White Opaque Wrap Around Label. PMS 446 and PMS Cool Gray 3 Print. Bottle: Thann Bottle.		<input checked="" type="checkbox"/> PMS 446 <input type="checkbox"/> PMS Cool Gray 3  <input type="checkbox"/> White Opaque Label	
	Date: 4/15/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: 
REVISION 1: <b>Revised Drug Facts</b>	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: <b>Revised INCI to Remove Translations for Aqua &amp; Parfum</b>	Date: 4/15/2020	<b>ALL ARTWORK IS PROPERTY OF GILCHRIST &amp; SOAMES</b>		
REVISION 3:	Date:	Approval Signature:		Date:
REVISION 4:	Date:			



## FRONT PANEL

<b>GILCHRIST &amp; SOAMES®</b> Somerset, NJ 08873 UK RG7 8DA www.gilchristsoames.com	<b>PROJECT: Gilchrist &amp; Soames Hand Sanitizer</b>			<b>PART NO: BKC Version</b>	
	Product: 1 fl oz Hand Sanitizer Label			INK COLORS: <input type="checkbox"/> CMYK <input checked="" type="checkbox"/> SPOT	
	Product Details: White Opaque Wrap Around Label. PMS 446 and PMS Cool Gray 3 Print. <b>Bottle: Thann Bottle.</b>			<input checked="" type="checkbox"/> PMS 446 <input type="checkbox"/> PMS Cool Gray 3	
	Date: 4/15/2020    Scale: 100%    Format: Adobe Illustrator    Graphics: MR			<input type="checkbox"/> White Opaque Label	
REVISION 1: Revised Drug Facts    Date: 4/7/2020				<b>PLEASE NOTE:</b> 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				<b>ALL ARTWORK IS PROPERTY OF GILCHRIST &amp; SOAMES®</b>	
REVISION 3:    Date:				Approval Signature:    Date:	
REVISION 4:    Date:					

30 mL NDC: 64596-222-13

## INSTANT HAND SANITIZER

hand sanitizer solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64596-222
<b>Route of Administration</b>	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
<b>WATER</b> (UNII: 059QF0K00R)	93.33 mL in 100 mL
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	0.23 g in 100 mL
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	0.08 g in 100 mL
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	0.02 g in 100 mL

<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.26 g in 100 mL
<b>POLYQUATERNIUM-37 (10000 MPA.S)</b> (UNII: 41QWS48DFN)	0.8 g in 100 mL
<b>ALCOHOL</b> (UNII: 3K9958V90M)	5 g in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64596-222-13	30 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: 5/2020

Gilchrist & Soames