

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.

BAC 1.35oz

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

Drug Facts	
Active Ingredient Benzalkonium Chloride 0.13%	Purpose Antimicrobial
Uses •Hand sanitizer to help reduce bacteria on the skin •Recommended for repeated use	
Warnings 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.	
Directions •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	
Other Information •Store below 110° F (43°C)	
Inactive ingredients Water, Ethyl Alcohol, Polyquaternium-37, Phenoxethanol, Caprylyl Glycol, Potassium Sorbate, Hexylene Glycol, Fragrance.	
Made in the USA Manufactured by Gilchrist & Soames® Somerset, NJ 08873 • UK RG7 8DA www.gilchristsoames.com	

BACK

Label Size: 1.27" X 2.31"
Corner Radius can be adjusted

 <p>Somerset, NJ 08873 UK RG7 8DA</p> <p>www.gilchristsoames.com</p>	PROJECT: Gilchrist & Soames Hand Sanitizer		PART NO: BKC Version	
	Product: 1.35 floz Hand Sanitizer Back Label		INK COLORS: <input type="checkbox"/> CMYK <input checked="" type="checkbox"/> SPOT	
	Product Details: White Opaque Front & Back Labels. PMS 446 and PMS Cool Gray 3 Print. Bottle: Agraria Bottle.		<input checked="" type="checkbox"/> PMS 446	<input checked="" type="checkbox"/> PMS Cool Gray 3
Date: 4/15/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: 	<input type="checkbox"/> 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. ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES
REVISION 2: Revised INCI to Remove Translations for Aqua & Parfum		Date: 4/15/2020		
REVISION 3:		Date:		
Approval Signature:			Date:	



FRONT

Label Size: 1.27" X 2.31"
 Corner Radius can be adjusted

GILCHRIST & SOAMES Somerset, NJ 08873 UK RG7 8DA www.gilchristsoames.com	PROJECT: Gilchrist & Soames Hand Sanitizer		PART NO: BKC Version	
	Product: 1.35 floz Hand Sanitizer Front Label		INK COLORS: <input type="checkbox"/> CMYK <input checked="" type="checkbox"/> SPOT	
	Product Details: White Opaque Front & Back Labels. PMS 446 and PMS Cool Gray 3 Print. Bottle: Agraria 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:	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 1: Revised Drug Facts Date: 4/7/2020			ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES	
REVISION 2: Revised INCI to Remove Translations for Aqua & Parfum Date: 4/15/2020			Approval Signature: _____ Date: _____	
REVISION 3: _____				

40 mL NDC: 64596-222-40

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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	0.02 g in 100 mL
WATER (UNII: 059QF0K00R)	93.33 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.23 g in 100 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.08 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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64596-222-40	40 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