

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.

1oz 30mL EtOH 77%

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.

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

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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Other information

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

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.

1 oz EtOH



BACK PANEL

<p>Somerset, NJ 08873 UK RG7 8DA</p> <p>www.gilchristsoames.com</p>	PROJECT: Gilchrist & Soames Hand Sanitizer		PART NO:	
	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. Bottle: Thann Bottle.				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.
White Opaque Label				
Date: 3/27/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR GCS20	ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES
REVISION 1: Revised to state: Manufactured for	Date: 3/25/2020	Approval Signature: _____ Date: _____		
REVISION 2: Revised Alcohol Content to Ethyl Alcohol 77.0% v/v	Date: 3/25/2020			
REVISION 3: Revised: The word INSTANT was missing	Date: 3/26/2020			
REVISION 4: Revised: Die Line now 3 " X 2". Centering Panels adjusted.	Date: 3/27/2020			



FRONT PANEL

GILCHRIST & SOAMES® Somerset, NJ 08873 UK RG7 8DA www.gilchristsoames.com	PROJECT: Gilchrist & Soames Hand Sanitizer			PART NO:	
	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. Bottle: Thann Bottle.			<input checked="" type="checkbox"/> PMS 446 <input checked="" type="checkbox"/> PMS cool Gray 3 <input type="checkbox"/> White Opaque Label	
	Date: 3/27/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR	
REVISION 1: Revised to state: Manufactured for			Date: 3/25/2020		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® Approval Signature: _____ Date: _____
REVISION 2: Revised Alcohol Content to Ethyl Alcohol 77.0% v/v			Date: 3/25/2020		
REVISION 3: Revised: The word INSTANT was missing			Date: 3/26/2020		
REVISION 4: Revised: Die Line now 3" X 2". Centering Panels adjusted.			Date: 3/27/2020		

30mL NDC: 64596-382-30

HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64596-382
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.1 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 g in 100 g
CARBOMER 980 (UNII: 4Q93RCW27E)	0.5 g in 100 g

GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 100 g
WATER (UNII: 059QF0KO0R)	25.4 g in 100 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64596-382-30	30 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/29/2020	

Labeler - Gilchrist & Soames (052683856)

Registrant - Gilchrist & Soames (052683856)

Establishment

Name	Address	ID/FEI	Business Operations
Gilchrist & Soames		052683856	manufacture(64596-382)

Revised: 6/2020

Gilchrist & Soames