

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.

1 gallon 3785mL 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.

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.

Other information

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


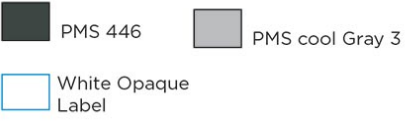
Directions

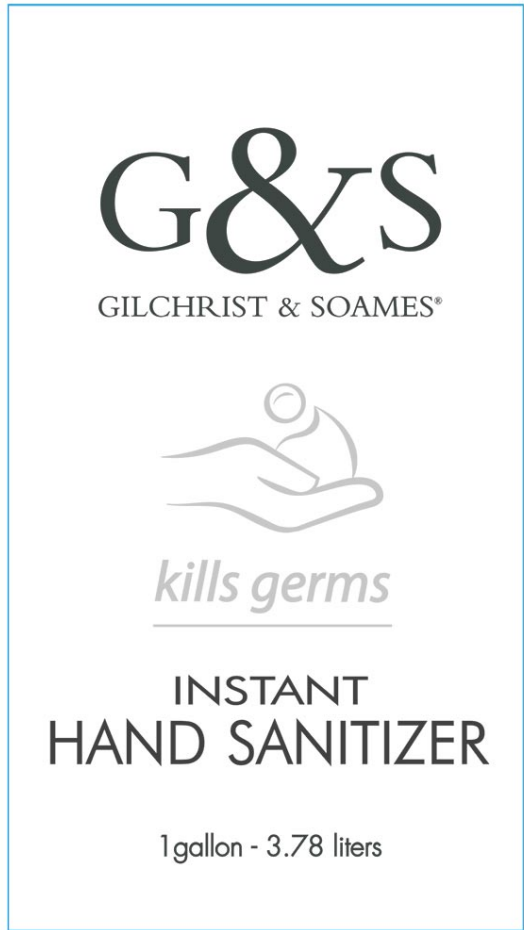
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

1 gallon EtOH

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 77% v/v.....	Antimicrobial
Uses	
•Hand sanitizer to help reduce bacteria on the skin	
Warnings	
Flammable. Keep away from fire or flame.	
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)	
•May discolor certain fabrics or surfaces	
Inactive ingredients	
Water (Aqua), Propylene Glycol, Glycerin, Isopropyl Myristate, Carbomer, Aminomethyl Propanol.	
<p>Made in the USA</p> <p>Manufactured for Gilchrist & Soames® Somerset, NJ 08873 • UK RG7 8DA www.gilchristsoames.com</p>	

BACK PANEL

 Somerset, NJ 08873 UK RG7 8DA www.gilchristsoames.com	PROJECT: Gilchrist & Soames Hand Sanitizer			PART NO:	
	Product: 1 Gallon 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: Gallon Bottle				
Date: 3/27/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR	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:	Date:		ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES		
REVISION 2:	Date:		Approval Signature: _____ Date: _____		
REVISION 3:	Date:				



FRONT PANEL

<p>GILCHRIST & SOAMES®</p> <p>Somerset, NJ 08873 UK RG7 8DA</p> <p>www.gilchristsoames.com</p>	PROJECT: Gilchrist & Soames Hand Sanitizer			PART NO:	
	Product: 1 Gallon 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: Gallon Bottle			<input checked="" type="checkbox"/> PMS 446 <input checked="" type="checkbox"/> PMS cool Gray 3	
	Date: 3/27/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR G&S20	<input type="checkbox"/> White Opaque Label
REVISION 1:	Date:			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:

3785mL NDC: 64596-382-99

<p>HAND SANITIZER</p> <p>alcohol solution</p>			
<p>Product Information</p>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64596-382
Route of Administration	TOPICAL		
<p>Active Ingredient/Active Moiety</p>			

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:64596-382-99	3785 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)