

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.

G&S Instant Hand Sanitizer 1.25oz 37mL

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.

 <p>Somerset, NJ 08873 UK RG7 8DA</p> <p>www.gilchristsoames.com</p>	PROJECT: Gilchrist & Soames Hand Sanitizer			PART NO: G&S Formulation	
	Product: 1.25 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.			<div>  PMS 446  PMS cool Gray 3 </div>	
	Date: 9/1/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: 	
REVISION 1: Revised Drug Facts Panel			Date: 9/1/2020		<p>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.</p> <p>ALL ARTWORK IS PROPERTY OF GILCHRIST & SOAMES™</p>
REVISION 2:			Date:		
REVISION 3:			Date:		
			Approval Signature:		Date:



FRONT PANEL

GILCHRIST & SOAMES® Somerset, NJ 08873 UK RG7 8DA www.gilchristsoames.com	PROJECT: Gilchrist & Soames Hand Sanitizer				PART NO: G&S Formulation	
	Product: 1.25 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.				<div> <div style="display: inline-block; width: 20px; height: 20px; background-color: black; margin-right: 5px;"></div> PMS 446 <div style="display: inline-block; width: 20px; height: 20px; background-color: gray; margin-left: 20px; margin-right: 5px;"></div> PMS cool Gray 3 </div>	
	Date: 9/1/2020	Scale: 100%	Format: Adobe Illustrator	Graphics: MR G&S 20	<div> <div style="display: inline-block; width: 20px; height: 20px; border: 1px solid black; margin-right: 5px;"></div> White Opaque Label </div>	
REVISION 1: Revised Drug Facts Panel				Date: 9/1/2020		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:				Date:		
REVISION 3:				Date:		

37 mL NDC:64596-388-12

HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64596-388
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	67 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64596-388-12	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	09/08/2020	

Labeler - Gilchrist & Soames (052683856)

Registrant - Gilchrist & Soames (052683856)

Establishment			
Name	Address	ID/FEI	Business Operations
Gilchrist & Soames		052683856	manufacture(64596-388)