

HAND SANITIZER- alcohol gel
Mayfield Consumer Products. LLC (MCP)

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.

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



Artwork is **Scale @ 100.0%**

Group ID : MCP005

Mayfield Consumer Products			Ticket : 229191		
Product Name : MCP005_1-8Sanitizer					
Product Description : 2-5/8" x 3-3/8" 1.8 oz. Hand Sanitizer Lab					
Product ID : 0000271346			Corner radius :		
Date : 4/16/2020		Time : 4:26:14 PM		Revision No.:	
		Operator : courtney@ilsesko01			
QC Artist	Barcode: It is the Client's responsibility to ensure the barcode scans.				
		Cyan	Magenta	Black	DIE

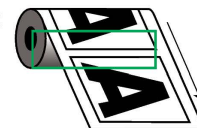
QUALITY ASSURANCE CHECK

Printer has checked this artwork for accuracy. Final approval is the client's responsibility. Please double-check for errors before release to any external supplier. Thereafter Printer cannot accept responsibility for any errors/omissions overlooked by the client or client's agent.

APPROVALS

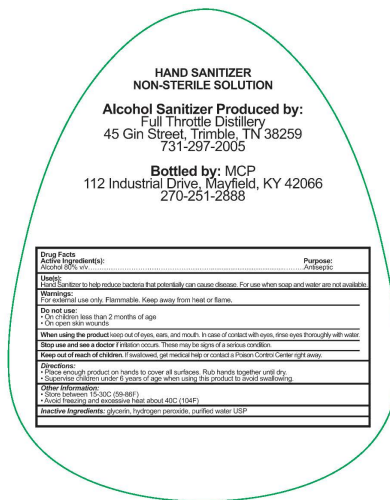
This Proof is not for color. This proof is for content only. The intention of this proof is to check the contents of the artwork. This file is not to be used to do any kind of editing.

Wind Direction :





Finish : Rolls

Out / Right 3



Artwork is **Scale @ 100.0%**

Group ID : MCP006

Mayfield Consumer Products			Ticket : 229189		
Product Name : MCP006_8ozSanBack					
Product Description : 2.87" x 2.27" 8 oz Hand Sanitizer Back					
Product ID : 0000271345			Corner radius :		
Date : 4/16/2020		Time : 4:15:14 PM		Revision No.:	
		Operator : courtney@ilsesko01			
QC Artist	Barcode: It is the Client's responsibility to ensure the barcode scans.		 Black	 DIE	

QUALITY ASSURANCE CHECK

Printer has checked this artwork for accuracy. Final approval is the client's responsibility. Please double-check for errors before release to any external supplier. Thereafter Printer cannot accept responsibility for any errors/omissions overlooked by the client or client's agent.

APPROVALS

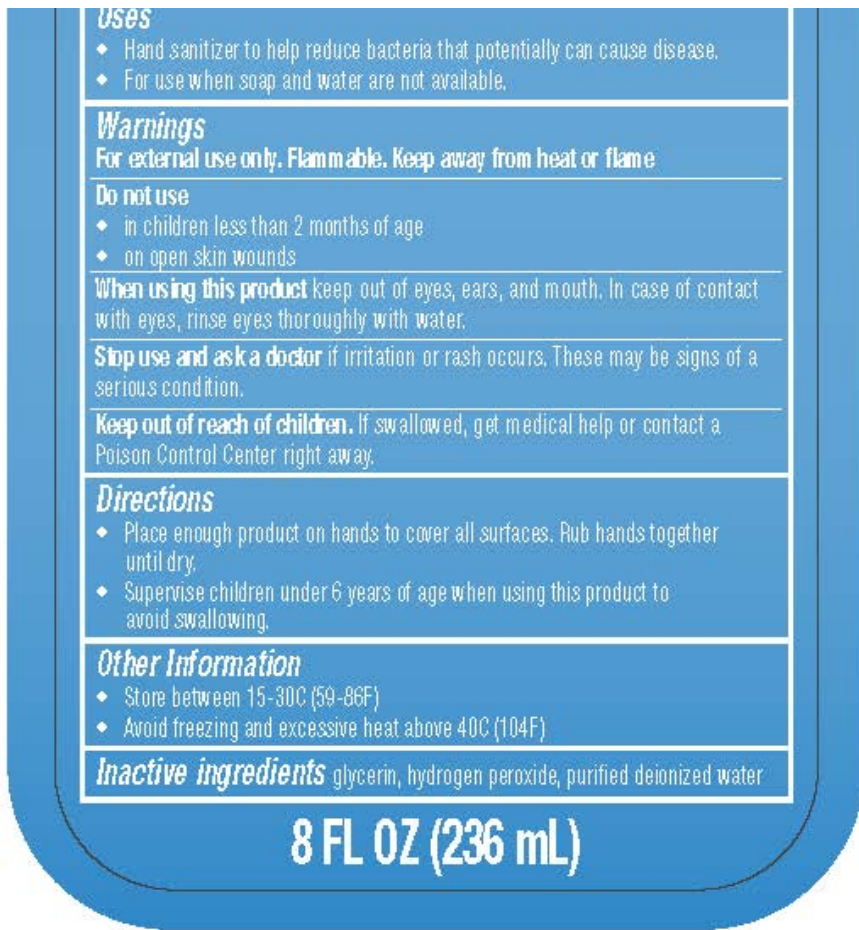
This Proof is not for color. This proof is for content only. The intention of this proof is to check the contents of the artwork. This file is not to be used to do any kind of editing.

Wind Direction :



Finish : Rolls





4.1613" Hgt.

2.2498" W

236 mL NDC: 76852-002-02

236 mL NDC: 76852-003-03

53.2 mL NDC: 76852-001-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76852-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL
--	---------	-----------------

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76852-001-01	53.2 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/29/2020	04/01/2021

FRONT OF BOTTLE

BACK OF BOTTLE

FULL THROTTLE DISTILLERY LABELS
***CENTER LABELS ON BOTTLE**
Renders are not scaled to size, for visual reference only.

LABEL WRAPS AROUND BOTTLE

P&G LABELS
***CENTER LABELS ON BOTTLE**
Renders are not scaled to size, for visual reference only.

LABEL WRAPS AROUND BOTTLE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	04/01/2021

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76852-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76852-002-02	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/29/2020	04/01/2021




FRONT OF BOTTLE



BACK OF BOTTLE



LABEL WRAPS AROUND BOTTLE



LABEL WRAPS AROUND BOTTLE

FULL THROTTLE DISTILLERY LABELS
*CENTER LABELS ON BOTTLE
Renders are not scaled to size, for visual reference only.

P&G LABELS
*CENTER LABELS ON BOTTLE
Renders are not scaled to size, for visual reference only.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	04/01/2021

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76852-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76852-003-03	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/29/2020	04/01/2021



FRONT OF BOTTLE



BACK OF BOTTLE

FULL THROTTLE DISTILLERY LABELS
*CENTER LABELS ON BOTTLE
Renders are not scaled to size, for visual reference only.

LABEL WRAPS AROUND BOTTLE



P&G LABELS
*CENTER LABELS ON BOTTLE
Renders are not scaled to size, for visual reference only.

LABEL WRAPS AROUND BOTTLE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	04/01/2021

Labeler - Mayfield Consumer Products, LLC (MCP) (047950351)

Registrant - Mayfield Consumer Products, LLC (047950351)

Establishment

Name	Address	ID/FEI	Business Operations
Mayfield Consumer Products, LLC (MCP)		047950351	repack(76852-001, 76852-002, 76852-003) , relabel(76852-002, 76852-001, 76852-003)

Revised: 4/2020

Mayfield Consumer Products, LLC (MCP)