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

	HAND SA	NIIIZER			
	NON-STERILE S	OLUTION			
	ALCOHOL ANTISEPTIC • 809	6 • TOPICAL SOLUTION			
	compliments of:	MCP			
Alcoh	HAND SANITIZER NON-ST ol Sanitizer Produced by: Full Throttle Distillery Bottled by: MCP 112 Industrial Drive, M	45 Gin Street, Trimble, TN 38259 731-297-2			
	Drug Facts Active Ingredient(s): Alcohol 80% v/v.	Purpose: Antiseptic			
	Use(s): Hand Sanitizer to help reduce bacteria that potentially can cause of	isease. For use when scap and water are not available.			
	Warnings: For external use only. Flammable. Keep away from heat or flame.				
	Do not use: • On children less than 2 months of age • On open skin wounds				
	When using the product keep out of eyes, ears, and mouth. In case				
	Stop use and see a doctor if irritation occurs. These may be s				
	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 about 40C (104F)				
	Inactive Ingredients: glycerin, hydrogen peroxide, purified v	rater LISP			

Artwork is Scale @ 100.0%

Group ID : MCP005

Mayfield (Consumer Products		Ticket : 229191			
Product N	lame : MCP005_1-8Sar	itizer				
Product D	Description : 2-5/8" x 3-3	/8" 1.8 oz. Hand Sanitizer Lab				
Product II	Product ID : 0000271346 Corner radius :					
Date : 4/1	6/2020 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				
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Artwor	k 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 Bac	k
Product ID : 0000271345	Corner radius :
Date : 4/16/2020 Time : 4:15:14 PM Revision No.:	Operator : courtney@ilsesko01
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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 Moi	etv			
-	lient Name		Basis of Strengtl	n Strength

ALCOHOL

	lients				
	Ingre		Strength		
GLYCERIN (UNII: PDC6A3C0OX) 1.45 mL in 100 ml					
HYDROGEN PEROXIDE (UNII: BBX060AN9V)0.125 mL in 100 mL					
WATER (UNII: 059C	(F0KO0R)				
Product Chara	cteristics				
Color		Score			
Shape		Size			
Flavor		Imprint Co	de		
Contains					
Packaging					
# Item Code	P	ackage Description		Marketing Start Date	Marketing End Date
		, DISPENSING; Type 0: Not	a Combination	04/29/2020	04/01/2021
01	Product				
			L THROTTLE DISTILLERY *CENTER LABELS ON t scaled to size, for visual refere	BOTTLE	*CENTER LABELS ON BOTT Renders are not scaled to si
		Renders are not	*CENTER LABELS ON t scaled to size, for visual refere	BOTTLE nce only. Not File Individua Alcohol Antisepti Topical Soluti d Sanitzer - Non-ste	*CENTER LABELS ON BOTT Renders are not scaled to si for visual reference or visual reference or nor rile solu
HAND	AK 172 kr	Renders are not	*CENTER LABELS ON tscaled to size, for visual references APS AROUND BOTTLE	BOTTLE nee only. Not For Individua Atchol Attispti Topical Soluti	*CENTER LABELS ON BOTT Renders are not scaled to si for visual reference of rise Solu- ritie Solu- ritie Solu- ritie solu- ritie solu- ritie solu-
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HAND SANITIZER

alcohol gel

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Product Type		HUMAN OTC DRUG	Item Code	(Source)	NE	DC:76852-002
Route of Administ		(ource)				
Route of Administ	ITAUUII	TOPICAL				
Active Ingredie	ent/Active Moi	ety				
	Ingred	ient Name		Basis of S	Strength	Strength
ALCOHOL (UNII: 3)	K9958V90M) (ALC	OHOL - UNII:3K9958V90M)	ALCOHOL		80 mL in 100 mL
Inactive Ingred	lients					
	Ing	redient Name			St	rength
GLYCERIN (UNII: P	DC6A3C0OX)			1.45	mL in 100 n	nL
HYDRO GEN PERO	XIDE (UNII: BBX06	0 AN9 V)		0.12	25 mL in 100	mL
WATER (UNII: 059C	F0KO0R)					
Product Chara	cteristics					
Color		Score				
Shape		Size				
Flavor		Imprint (Code			
Contains		_				
Packaging						
# Item Code		Package Description		Market	ing Start	Marketing End
		ruchage Description		D	ate	Date
	236 mL in 1 BOTT Product	LE, DISPENSING; Type 0: N	ot a Combination	D 04/29/202		
1 NDC:76852-002-		LE, DISPENSING; Type 0: N	ot a Combination	0 4/29 /20 2		Date 0 4/0 1/20 21 P&G LABEL *CENTER LABELS ON BOTTL
1 NDC:76852-002-	Product	LE, DISPENSING; Type 0: N	ULL THROTTLE DISTILLE	0 4/29 /20 2		Date 0 4/0 1/20 21 P&G LABEL *CENTER LABELS ON BOTTI Renders are not scaled to siz for visual reference ont solutions Solutions
1 NDC:76852-002- 02	Product	LE, DISPENSING; Type 0: N	ULL THROTTLE DISTILLE *CENTER LABELS (not scaled to size, for visual re vraps AROUND BOTTLE	0 4/29 /20 2	0 Not For Individual State Not For Individual	Date 0 4/0 1/20 21

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 SANIT alcohol gel	IZER							
Product Informa	ation							
Product T ype		HUMAN OTC DI	RUG	Item Code	(Source	2)	NDC:76852-003	
Route of Administr	ation	TOPICAL						
Active Ingredier	nt/Active Moie	t v /						
Active ingretiel		ent Name			Basis	of Strength	Strength	
ALCOHOL (UNII: 3K	-		958V90M		ALCOHO		80 mL in 100 mL	
Inactive Ingredi	ents							
Ingredient Name Strength						Strength		
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)0.125 mL in 100 mL					00 mL			
WATER (UNII: 059QI	F0KO0R)							
Product Charac	teristics							
Color			Score					
Shape			Size					
Flavor Imp				Imprint Code				
Contains								
Packaging								
# Item Code		Package Desc	ription		Mark	eting Start Date	Marketing End Date	
1 NDC:76852-003- 03	852-003- 236 mL in 1 BOTTLE, PUMP; Type Product			Combination 04/29/2020 04/01/2			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)