HAND SANITIZER- alcohol liquid Rapid Cure Technologies, Inc.

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.

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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

WHO-recommended formulation



Kills Harmful Bacteria and Germs

Non-sterile Solution

Alcohol Antiseptic 80%

Topical Solution



MANUFACTURED & DISTRIBUTED BY:

RAPID CURE TECHNOLOGIES, INC. 7030 FLY RD, EAST SYRACUSE, NY 13057 (888) 847-3610 / <u>WWW.RAPIDCURETECHNOLOGIES.COM</u> RCT 01 1274 HS LOT#

1890 mL NDC: 75722-002-02

HAND SANITIZER

alcohol liquid

Product Information

Drug Facts



Active Ingredient: Alcohol 80% by volume

Purpose: Antiseptic

Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.

Warnings:

- For external use only.
- Do not use on children less than 2 months of age.
- Do not use on open skin wounds.
- Flammable. Keep away from source of heat, fire, or flame.
- When using this product keep out of eyes, ears, and mouth. If contact occurs, rinse thoroughly with water.
- Stop use and ask a doctor if irritation or redness develops and lasts. These may be signs of a serious condition.
- If swallowed, get medical help or contact a Poison Control Center immediately.

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

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

0.5 gallons (1.89 liters)

Pr	roduct T ype			HUMAN OTC DRUG	Item Co	de (Source	e) I	NDC:7	5722-003	
Route of Administration				TOPICAL						
A	ctive Ingred	lient/Ac	ctive Moie	ty						
Ingred				lient Name		Basis	Basis of Strength		Strength	
ALCOHOL (UNII: 3K9958V90M) (ALC				OHOL - UNII:3K9958V9	OL - UNII:3K9958V90M) ALCOHO		DL	80	mL in 100 mL	
In	active Ingro	edients								
	0		Ing	redient Name			Strength			
GI	L YCERIN (UNII:	PDC6A3					1.45 mL in 100 mL			
HY	DROGEN PER	O XIDE (U	JNII: BBX06	DAN9V)			0.125 mL in 100 mL			
W	ATER (UNII: 05	9QF0KO) R)							
Pa	ackaging									
#	Item Code			Package Descrip	otion		Marketir Start Da		Marketing En Date	
1	NDC:75722- 003-01	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					03/30/2020			
2	NDC:75722- 003-02	18925 mL in 1 PAIL; Type 0: Not a Combination Product				03/30/2020				
3	NDC:75722- 003-03	189250 mL in 1 DRUM; Type 0: Not a Combination Product				03/30/2020				
4	NDC:75722- 003-04	1003025 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product				03/30/2020				
5	NDC:75722- 003-05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				03/30/2020				
6	NDC:75722- 003-06	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				03/30/2020				
7	NDC:75722- 003-07 NDC:75722-	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				03/30/2020				
8	NDC:75722- 003-08 NDC:75722-	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product				03/30/2020				
9	003-09	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product				03/30/2020				
10	003-10	947 mL	IN 1 BOTTLE	, SPRAY; Type 0: Not a	Combination Prod	luct	03/30/2020			
M	larketing									
	Marketing Category Applicat			on Number or Monog	raph Citation	Aation Marketing Start Date		Marketing End Date		
I	Marketing Cal	legury	ripplicau	on manifer of monog	, up n enauen	Marketin	Sourcoute	mai	at the Life Date	

Labeler - Rapid Cure Technologies, Inc. (017489374)

Establishment										
Name	Address	ID/FEI	Business Operations							

Rapid Cure Technologies, Inc	•	
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Revised: 4/2020

Rapid Cure Technologies, Inc.

manufacture(75722-003)