

HAND SANITIZER- isopropyl alcohol gel
RAPHA HEALTH NETWORK INTERNATIONAL

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 70% 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

236 ml NDC:78527-0

Drug Facts:	
Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antiseptic
Uses: For handwashing to decrease bacteria on the skin that could cause disease. Recommended for repeated use.	
Warnings FOR EXTERNAL USE ONLY - HANDS Flammable, keep away from fire or flame. Do not use in the eyes. If this happens, rinse thoroughly with water. Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours. Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away.	
Directions- Wet hands thoroughly with product. Rub hands together until dry. Apply a small amount over skin as often as needed. No-rinse. Supervise children under 6 years in the use of this product.	
Inactive Ingredients Alcohol, whater, glycerin, carbomer, triethanolamine, aloe barbadensis leaf juice.	



Rapha Health
NETWORK INTERNATIONAL

RAPHA HEALTH
Hands and Body Sanitizer
Ethyl Alcohol 70% :

- *Kills 99.999% of all Viruses*
- *Gentle enough to be applied on face.*
- *Proven to keep working hours after application!*
- *Help prevent infections.*
- *Proven to be gentle on skin tissue and Non-irritating.*





Hands and Body
SANITIZER
Ethyl Alcohol 70%



8 FL OZ (236 ml)

Manufactured by
RAPHA HEALTH NETWORK
INTERNATIONAL, INC.
FL. U.S.A. 33166
Florida Department of Agriculture
& Consumer Services
Division of Food Safety -
License Number 345970

www.raphahealth.net



6 43934 67925 8

Drug Facts:

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antiseptic

Uses:

For handwashing to decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

FOR EXTERNAL USE ONLY - HANDS

Flammable, keep away from fire or flame.

Do not use in the eyes. If this happens, rinse thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours.

Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away.

Directions- Wet hands thoroughly with product. Rub hands together until dry. Apply a small amount over skin as often as needed. No-rinse. Supervise children under 6 years in the use of this product.

Inactive Ingredients

Alcohol, whater, glycerin, carbomer, triethanolamine, aloe barbadensis leaf juice.



Rapha Health
NETWORK INTERNATIONAL



**Hands and Body
SANITIZER**

Ethyl Alcohol 70%



8 FL OZ (236 ml)

- RAPHA HEALTH
Hands and Body Sanitizer
Ethyl Alcohol 70% :**
- **Kills 99.999% of all Viruses**
 - **Gentle enough to be applied on face.**
 - **Proven to keep working hours after application!**
 - **Help prevent infections.**
 - **Proven to be gentle on skin tissue and Non-irritating.**

Manufactured by
RAPHA HEALTH NETWORK
INTERNATIONAL, INC.
FL. U.S.A. 33166
Florida Department of Agriculture
& Consumer Services
Division of Food Safety -
License Number 345970

www.raphahealth.net



HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78527-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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:78527-001-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Drug Facts:

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antiseptic

Uses:
For handwashing to decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings
FOR EXTERNAL USE ONLY - HANDS
Flammable, keep away from fire or flame.
Do not use in the eyes. If this happens, rinse thoroughly with water.
Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours.
Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away.

Directions- Wet hands thoroughly with product. Rub hands together until dry. Apply a small amount over skin as often as needed. No-rinse. Supervise children under 6 years in the use of this product.

Inactive Ingredients
Alcohol, water, glycerin, carbomer, triethanolamine, aloe barbadensis leaf juice.

RAPHa HEALTH
Hands and Body Sanitizer
Ethyl Alcohol 70%

- Kills 99.999% of all Viruses
- Gentle enough to be applied on face.
- Proven to keep working hours after application!
- Help prevent infections.
- Proven to be gentle on skin tissue and Non-irritating.

Manufactured by
RAPHa HEALTH NETWORK
INTERNATIONAL, INC.
FL. U.S.A. 33166
Florida Department of Agriculture
& Consumer Services
Division of Food Safety -
License Number 345970

www.raphahealth.net

8 FL OZ (236 ml)

6 43934 67925 8

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - RAPHa HEALTH NETWORK INTERNATIONAL (613704795)

Establishment

Name	Address	ID/FEI	Business Operations
APHEX BIOCLEANSE SYSTEMS, INC		012445467	manufacture(78527-001)

Revised: 6/2020

RAPHA HEALTHNETWORK INTERNATIONAL