HAND SANITIZER- is opropyl alcohol solution Massachusetts General Hospital PET Center

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 (0.725% 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 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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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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)

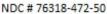
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Massachusetts General Hospital PET Center

Isopropyl Alcohol Antiseptic 75% Topical Solution





Lot: C00-000000

500 mL Expires: 4/1/2021

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Active ingredient[s]

Purpose

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Massachusetts General Hospital PET Center

Isopropyl Alcohol Antiseptic 75% **Topical Solution**

NDC # 76318-472-10



Lot: C00-000000

Expires: 4/1/2021 1000 mL

Drug Facts

Active ingredient[s]

Purpose

Isopropyl alcohol 75% v/v......Antiseptic

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Massachusetts General Hospital PET Center

Isopropyl Alcohol Antiseptic 75% **Topical Solution**



NDC # 76318-472-16

Antiseptic Hand Rub Non-sterile Solution

Lot: C00-000000

Expires: 12/31/2020 16 oz

Massachusetts General Hospital PET Center

Isopropyl Alcohol Antiseptic 75% Topical Solution

NDC # 76318-472-32



Lot: C00-000000

32 oz Expires: 12/31/2020

HAND SANITIZER

isopropyl alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76318-472	
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: PDC6 A3C0 OX)	0.725 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76318-472- 50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
2	NDC:76318-472- 10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
3	NDC:76318-472- 16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
4	NDC:76318-472- 32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		

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

Labeler - Massachusetts General Hospital PET Center (156293698)

Establishment				
Name	Address	ID/FEI	Business Operations	
Massachusetts General Hospital PET Center		156293698	manufacture(76318-472)	

Revised: 4/2020 Massachusetts General Hospital PET Center