

HAND SANITIZER- isopropyl alcohol solution
Sysmex Reagents America, Incorporated

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.

Hand Sanitizer
Non-sterile Solution

<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.

<p class="First">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.</p><p>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:</p><ol class="LittleAlpha">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.Glycerol (1.45% v/v).Hydrogen peroxide (0.125% v/v).Sterile distilled water or boiled cold water.<p>The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.</p>

Active Ingredient(s)

Isopropyl Alcohol 75% 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

NOT FOR SALE
NDC: 75474-001-01
Isopropyl Alcohol
Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution
250 mL

MANUFACTURED BY:
SYSMEX REAGENTS AMERICA
TWO SYSMEX WAY
MUNDELEIN, IL 60060 USA

Questions?
In the U.S., call 1-888-879-7639

LOT: Y0002 MFR: 12-01-2021
PN: SYSAN-20

Drug Facts
Active Ingredients Isopropyl Alcohol 75% v/v
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For 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 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.
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
Formula is consistent with World Health Organization recommendation

250 mL NDC: 75474-001-01

Package Label - Principal Display Panel

NOT FOR SALE
NDC: 75474-001-02
Isopropyl Alcohol
Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution
1000 mL (1L)

MANUFACTURED BY:
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TWO SYSMEX WAY
MUNDELEIN, IL 60060 USA

Questions?
In the U.S., call 1-888-879-7639

LOT: Y0002 MFR: 12-01-2021
PN: SYSAN-20

Drug Facts
Active Ingredients Isopropyl Alcohol 75% v/v
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For water are not available
Warnings For external use only. Flammable. Keep away from heat or fire 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 thoroughly with water Stop use and ask a doctor if irritation or rash occurs. These may be: Keep out of reach of children If swallowed, get medical help or contact
Directions Place enough product on hands to cover all surfaces. Rub hands together until Supervise children under 6 years of age when using this product to avoid swallow
Other Information Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive Ingredients glycerin, hydrogen peroxide, purified water USP
Formula is consistent with World Health Organization recommendation

1000 mL NDC: 75474-001-02

Package Label - Principal Display Panel

NOT FOR SALE
NDC: 75474-001-03
Isopropyl Alcohol
Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution
16 oz

MANUFACTURED BY:
SYSMEX REAGENTS AMERICA
TWO SYSMEX WAY
MUNDELEIN, IL 60060 USA

Questions?
In the U.S., call 1-888-879-7639

LOT: Y0002 MFR: 12-01-2021
PN: SYSAN-20

Drug Facts
Active Ingredients Isopropyl Alcohol 75% v/v
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For 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 thoroughly with water Stop use and ask a doctor if irritation or rash occurs. These may be significant Keep out of reach of children If swallowed, get medical help or contact
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 swallow
Other Information Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive Ingredients glycerin, hydrogen peroxide, purified water USP
Formula is consistent with World Health Organization recommendation

473.176 mL (16oz) NDC: 75474-001-03

Package Label - Principal Display Panel

NOT FOR SALE
NDC: 75474-001-04
Isopropyl Alcohol
Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution
32 oz

MANUFACTURED BY:
 SYSMEX REAGENTS AMERICA
 TWO SYSMEX WAY
 MUNDELEIN, IL 60060 USA

Questions?
 In the U.S., call 1-888-879-7639

LOT: Y0002 MFR: 12-01-2021
 PN: SYSAN-20

Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/v

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when 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, rinse thoroughly with water

Stop use and ask a doctor if irritation or rash occurs. These may be signs of an allergic reaction

Keep out of reach of children If swallowed, get medical help or contact your poison control center

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

Formula is consistent with World Health Organization recommendations

946.35 mL (32oz) NDC: 75474-001-04

HAND SANITIZER				
isopropyl alcohol solution				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75474-001	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
Hydrogen Peroxide (UNII: BBX060AN9V)				
Water (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75474-001-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75474-001-	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination	04/20/2020	

2	02	Product	04/20/2020	
3	NDC:75474-001-03	473.176 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	
4	NDC:75474-001-04	946.35 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/20/2020	

Labeler - Sysmex Reagents America, Incorporated (834695454)

Registrant - Sysmex Reagents America, Incorporated (834695454)

Establishment

Name	Address	ID/FEI	Business Operations
Sysmex Reagents America, Incorporated		834695454	manufacture(75474-001)

Revised: 4/2020

Sysmex Reagents America, Incorporated