

CAREPURE 01- isopropyl alcohol liquid
Carestream Health, 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. 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 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.

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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

Isopropyl Alcohol Antiseptic 75% Topical Solution Antiseptic Hand Rub Non-sterile Solution 208198 mL (55 gal) FDA Code # 31382-963-01	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.
	Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none">• 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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	Inactive ingredients glycerin, hydrogen peroxide, purified water USP

CarestreamCarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

60 mL
FDA Code #
31382-963-02

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

80 mL
FDA Code #
31382-963-03

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution

120 mL
 FDA Code #
 31382-963-04

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.

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.

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

Carestream

CarePure Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution

240 mL (8oz)
 FDA Code #
 31382-963-05

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.

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.

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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

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

500 mL
FDA Code #
31382-963-06

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> 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.
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

1000 mL (1 L)
FDA Code #
31382-963-07

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> 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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Other information <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution

4000 mL (4L)
 FDA Code #
 31382-963-08

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution

5000 mL (5 L)
 FDA Code #
 31382-963-09

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

10000 mL (10 L)

FDA Code #
31382-963-10

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

7571 mL (2 gal)

FDA Code #
31382-963-11

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> • 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.
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

18927 mL (5 gal)
FDA Code #
31382-963-12

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> 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.
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**
Antiseptic Hand Rub
Non-sterile Solution

250 mL
FDA Code #
31382-963-13

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.
Warnings For external use only. Flammable. Keep away from heat or flame Do not use <ul style="list-style-type: none"> 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.
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Carestream

CarePure Hand Sanitizer

CAREPURE 01

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31382-963
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)		0.725 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31382-963-01	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:31382-963-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:31382-963-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:31382-963-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:31382-963-05	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:31382-963-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:31382-963-07	1000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
8	NDC:31382-963-08	4000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
9	NDC:31382-963-09	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
10	NDC:31382-963-10	10000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
11	NDC:31382-963-11	7571 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
12	NDC:31382-963-12	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
13	NDC:31382-963-13	250 mL in 1 BOTTLE; 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 - Carestream Health, Inc. (793169512)