

HAND SANITIZER- isopropyl alcohol gel

Sustainable Tech LLC

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

60 ml NDC: 77282-333-02

Drug Facts
Active Ingredients
 Isopropyl Alcohol 75% w/w ... Antiseptic

Use[s]
 Health care personnel hand rub to help reduce bacteria that potentially can cause disease

Warnings
 For external use only. Keep away from reach of children. Flammable. Keep away from heat or flame. Do not use on children less than 2 months of age and 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.

Inactive Ingredients
 glycerin, hydrogen peroxide, purified water USP



Alcohol Antiseptic 75%
 Topical Solution

ANTISEPTIC
HAND RUB
 Non-Sterile Solution

Health Care Personnel Hand Rub to help reduce bacteria that can cause disease

SUSTAINABLE
TECH

60ml
 Drug Code: 77282-333-02 | To order visit www.saath.com

Made in the U.S.A.

Riverside, California | FDA National Drug Code

118ml NDC: 77282-333-04



Drug Facts

Active Ingredients

Isopropyl Alcohol 75% w/v ... Antiseptic

Use[s]

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

Warnings

For external use only. Keep away from reach of children. Flammable. Keep away from heat or flame. Do not Use on Children less than 2 months of age and 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.

Inactive Ingredients

glycerin, hydrogen peroxide, purified water USP

118ml



Drug Facts

Active Ingredients

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. Keep away from reach of children. Flammable. Keep away from heat or flame. Do not Use on Children less than 2 months of age and 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.

Inactive Ingredients

glycerin, hydrogen peroxide, purified water USP

236mL



Alcohol Antiseptic 75%
Topical Solution

ANTISEPTIC
HAND RUB
Non-Sterile Solution

MADE IN
FDA
REGISTERED
FACILITY

Made in
the U.S.A.

Health Care Personnel Hand Rub to help reduce bacteria that
can cause disease

SUSTAINABLE
TECH

236mL

77282-333-08 | To order visit www.saafr.com

Kenilworth, California | FDA National Drug Code: 77282-333-08



Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/vAntiseptic

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 on Children less than 2 months of age and 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



473mL



Drug Facts

Active Ingredients

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. Keep away from reach of children. Flammable.
Keep away from heat or flame. Do not Use on Children less than 2
months of age and 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.

Inactive Ingredients

glycerin, hydrogen peroxide,
purified water USP



Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/vAntiseptic

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 on Children less than 2 months of age and 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



946ml

Isopropyl Alcohol
Antiseptic 75%
**ANTISEPTIC
HAND RUB**

Non-Sterile Solution



Health Care Personnel Hand Rub to help reduce bacteria that can cause disease



**SUSTAINABLE
TECH**

FDA - National Drug Code: 77282-333-32

Riverside, California. To order visit www.saafh.com

946ml

3785ml NDC:77282-333-11

Isopropyl Alcohol Antiseptic 75% Topical Solution



ANTISEPTIC HAND RUB Non-Sterile Solution



Health Care Personnel Hand Rub to help reduce bacteria that can cause disease.



SUSTAINABLE
TECH

3.78L (3785ml)

FDA - National Drug Code:
77282-333-01
Riverside, California.
To order visit
www.saafh.com

Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/vAntiseptic

Purpose

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 on Children less than 2 months of age and 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
[www.https://SustainableTechLLC.com](https://SustainableTechLLC.com)



1 Gal (3.78L)

To Order: <https://saafh.com>

Isopropyl Alcohol Antiseptic 75% Topical Solution



ANTISEPTIC HAND RUB Non-Sterile Solution



Health Care Personnel Hand Rub to help reduce bacteria that can cause disease.



SUSTAINABLE
TECH

18.9L (18927ml)

FDA - National Drug Code:
77282-333-05
Riverside, California.
To order visit
www.saaafh.com

Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/vAntiseptic

Purpose

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 on Children less than 2 months of age and 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
www.https://SustainableTechLLC.com



7 88000 44573 0

5Gal (18.9L)

To Order: [https://saaafh.com](http://saaafh.com)

Isopropyl Alcohol Antiseptic 75% Topical Solution



ANTISEPTIC HAND RUB Non-Sterile Solution



Health Care Personnel Hand Rub to help reduce bacteria that can cause disease.



SUSTAINABLE
TECH

209L (208197ml)

FDA - National Drug Code:
77282-333-55
Riverside, California.
To order visit
www.saafh.com

Drug Facts

Active Ingredients

Isopropyl Alcohol 75% v/vAntiseptic

Purpose

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 on Children less than 2 months of age and 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
www.https://SustainableTechLLC.com



7 88000 44574 7
55Gal (207.9L)

To Order: [https://saafh.com](http://saafh.com)

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77282-333
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
POLYQUATERNIUM-10 (10000 MPA.S AT 2%) (UNII: PI1STR9QYH)	1.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 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:77282-333-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
2	NDC:77282-333-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
3	NDC:77282-333-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
4	NDC:77282-333-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
5	NDC:77282-333-20	591 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
6	NDC:77282-333-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
7	NDC:77282-333-11	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
8	NDC:77282-333-15	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
9	NDC:77282-333-55	208197 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	

Marketing Information

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

Labeler - Sustainable Tech LLC (100850422)

Registrant - Sustainable Tech LLC (100850422)

Establishment

Name	Address	ID/FEI	Business Operations
Sustainable Tech LLC		100850422	manufacture(77282-333)

Revised: 5/2020

Sustainable Tech LLC