

**HAND SANITIZER LIQUID- ethanol alcohol liquid****HAND SANITIZER GEL- alcohol (ethanol) gel****TenSan**

*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.*

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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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 80% 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, purified water USP

**1022 L NDC 77175-001-01**

1022 L NDC 77175-001-01

<b>Drug Facts</b>	
<b>Active Ingredients:</b>	<b>Purpose</b>
Alcohol (70%)	Antiseptic, Hand Sanitizer
<b>Uses</b>	
A Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only	
Flammable Keep away from fire, flames, or sparks	
Do not use on children under 2 months of age. Do not use on open skin wounds.	
When using this product keep out of eyes, ears, and mouth. In case of contact rinse eyes thoroughly with water. Stop use and ask a doctor if rash or irritation occurs.	
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 appears on the skin. These may be signs of serious condition	
<b>Directions</b>	
Place enough product on hands to cover all surfaces. Rub hands together until dry.	
Children under 6 years of age should be supervised by adult when applying this product to avoid swallowing.	
<b>Other Information</b> - store below 110 degrees Fahrenheit or 43 degrees Celcius	
<b>Inactive ingredients:</b> purified water, acrylates copolymer, glycerine	
<b>Questions or Comments:</b>	
423-304-9564	
Manufactured by TenSan	
Hixson, TN 37343	
1022 L NDC: 77175-001-01	

**1022 L NDC 77175-002-02**

1022 L NDC 77175-002-02

## Drug Facts

### Active Ingredients:

Alcohol (80%)

### Purpose

Antiseptic, Hand Sanitizer

### Uses

A 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 fire, flames, or sparks

**Do not use** on children under 2 months of age. Do not use on open skin wounds.

**When using this product** keep out of eyes, ears, and mouth. In case of contact rinse eyes thoroughly with water. Stop use and ask a doctor if rash or irritation occurs.

**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 appears on the skin. These may be signs of serious condition

### Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Children under 6 years of age should be supervised by adult when applying this product to avoid swallowing.

**Other Information** - store below 110 degrees Fahrenheit or 43 degrees Celcius

**Inactive ingredients:** purified water, glycerine

### Questions or Comments:

423-304-9564

Manufactured by TenSan

Hixson, TN 37343

**1022 L NDC:77175-002-02**

<b>Drug Facts</b>	
<b>Active Ingredients:</b>	<b>Purpose</b>
Alcohol (80%)	Antiseptic,Hand Sanitizer
<b>Uses</b>	
A Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only	
Flammable Keep away from fire, flames, or sparks	
Do not use on children under 2 months of age. Do not use on open skin wounds.	
When using this product keep out of eyes, ears, and mouth. In case of contact rinse eyes thoroughly with water. Stop use and ask a doctor if rash or irritation occurs.	
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 appears on the skin. These may be signs of serious condition	
<b>Directions</b>	
Place enough product on hands to cover all surfaces. Rub hands together until dry.	
Children under 6 years of age should be supervised by adult when applying this product to avoid swallowing.	
<b>Other Information</b> - store below 110 degrees Farenheit or 43 degrees Celcius	
<b>Inactive ingredients:</b> purified water,acrylates copolymer, glycerine	
<b>Questions or Comments:</b>	
423-304-9564	
Manufactured by TenSan	
Hixson, TN 37343	
1022 L NDC: 77175-003-01	

1022 L NDC 77175-003-01

## HAND SANITIZER LIQUID

ethanol alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77175-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	766.46 L in 1021.95 L

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	14.8 L in 1021.95 L
ISOPROPYL ALCOHOL (UNII: ND2M416302)	51.1 L in 1021.95 L
WATER (UNII: 059QF0KO0R)	189.64 L in 1021.95 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77175-002-02	1022 L in 1 TANK; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

## HAND SANITIZER GEL

alcohol (ethanol) gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77175-001
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	664.3 L in 1021.95 L

## Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	51.1 L in 1021.95 L
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	51.1 L in 1021.95 L
GLYCERIN (UNII: PDC6A3C0OX)	14.8 L in 1021.95 L
WATER (UNII: 059QF0KO0R)	240.7 L in 1021.95 L

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77175-001-01	1022 L in 1 TANK; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

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

## HAND SANITIZER GEL

alcohol (ethanol) gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77175-003
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	766.5 L in 1021.95 L

### Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	51.1 L in 1021.95 L
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	51.1 L in 1021.95 L
GLYCERIN (UNII: PDC6A3C0OX)	14.8 L in 1021.95 L
WATER (UNII: 059QF0KO0R)	138.5 L in 1021.95 L

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77175-003-01	1022 L in 1 TANK; Type 0: Not a Combination Product	05/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

**Labeler** - TenSan (027499464)

**Registrant** - TenSan (027499464)

## Establishment

Name	Address	ID/FEI	Business Operations
TenSan		027499464	manufacture(77175-001, 77175-002, 77175-003)