

**HAND SANITIZER GEL- isopropyl alcohol gel**  
**AXIS CONNECT US 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.*

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**Hand sanitizer gel**

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**

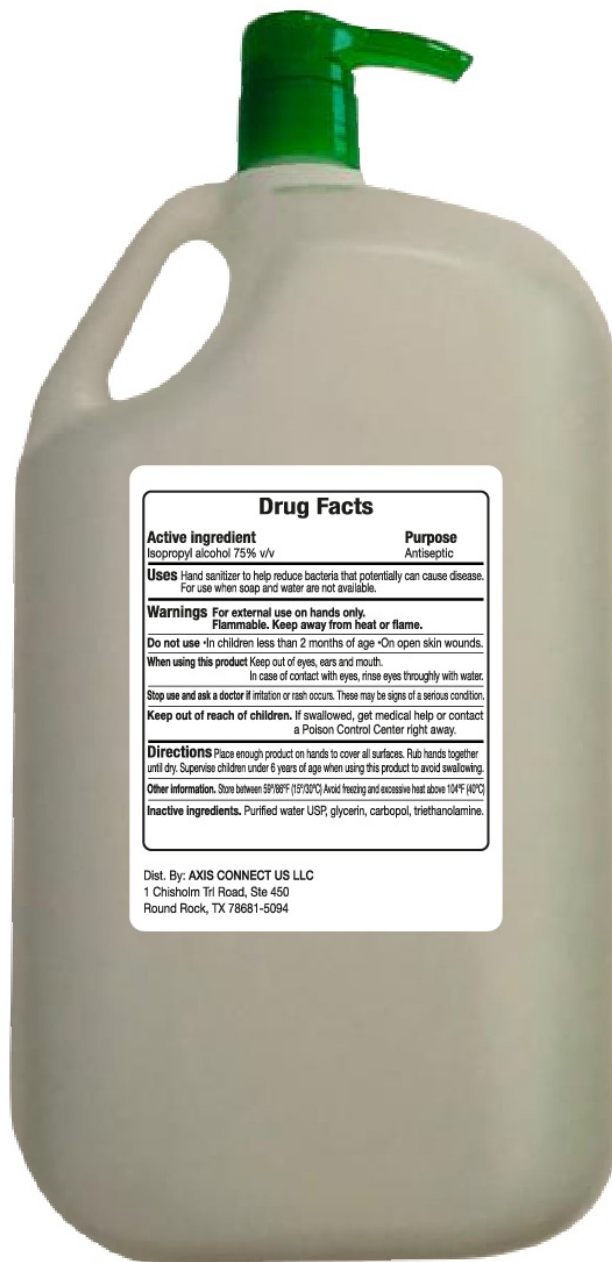
glycerin, hydrogen peroxide, purified water USP

**INACTIVE INGREDIENTS**

Purified water USP, glycerin, carbopol, triethanolamine

**Package Label - Principal Display Panel**

3785 ml NDC: 78456-100-51



**Drug Facts**

Active ingredient	Purpose
Isopropyl alcohol 75% v/v	Antiseptic

**Uses** Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings** For external use on hands 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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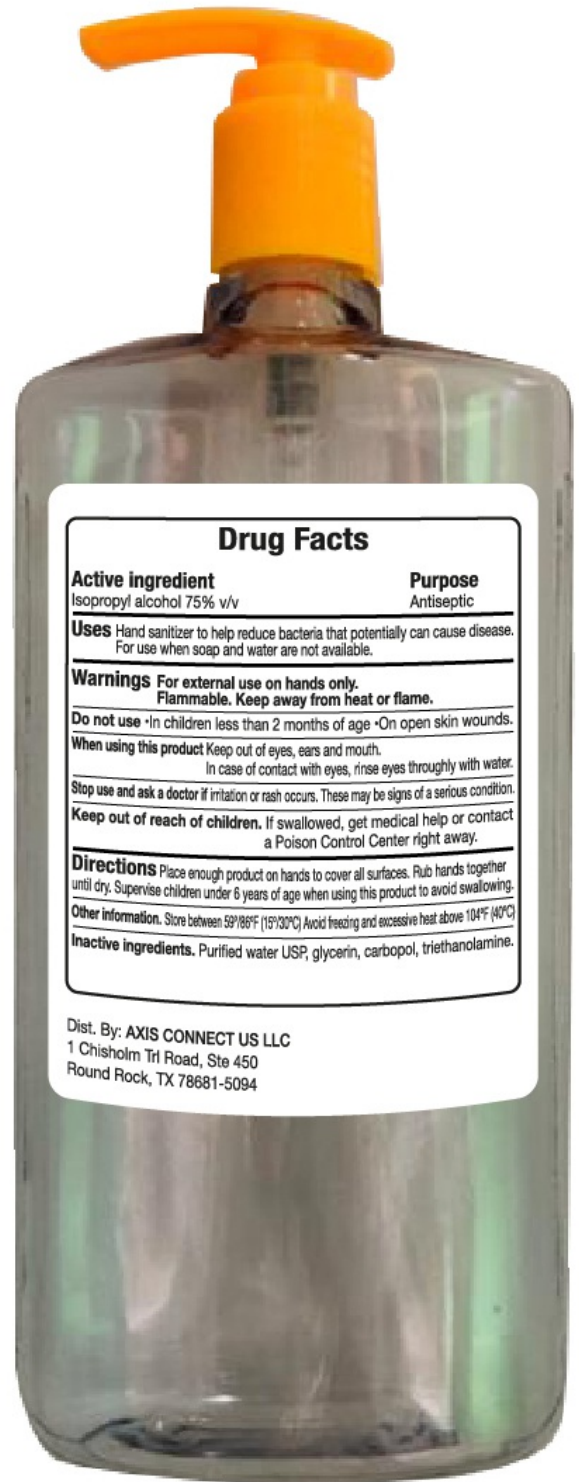
**Directions** Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information.** Store between 59°/68°F (15°/20°C). Avoid freezing and excessive heat above 104°/40°C.

**Inactive ingredients.** Purified water USP, glycerin, carbopol, triethanolamine.

Dist. By: AXIS CONNECT US LLC  
1 Chisholm Tri Road, Ste 450  
Round Rock, TX 78681-5094

500 ml NDC: 78456-100-41



### Drug Facts

Active ingredient	Purpose
Isopropyl alcohol 75% v/v	Antiseptic

**Uses** Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings** For external use on hands 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 59°/86°F (15°/30°C) Avoid freezing and excessive heat above 104°F (40°C)

**Inactive ingredients.** Purified water USP, glycerin, carbopol, triethanolamine.

Dist. By: AXIS CONNECT US LLC  
1 Chisholm Trl Road, Ste 450  
Round Rock, TX 78681-5094

100 mL NDC: 78456-100-21



HAND SANITIZER GEL			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78456-100
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
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78456-100-51	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/06/2020	
2	NDC:78456-100-41	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/06/2020	
3	NDC:78456-100-21	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/06/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/06/2020	

**Labeler** - AXIS CONNECT US LLC (081057471)

**Registrant** - AXIS CONNECT US LLC (081057471)

## Establishment

Name	Address	ID/FEI	Business Operations
Grupo Kurin, S. De R.L. De C.V.		812898073	manufacture(78456-100)

Revised: 7/2020

AXIS CONNECT US LLC