

## **HAND SANITIZER- isopropyl alcohol liquid**

### **Chemical Consultants 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.*

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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. 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.

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**

**IBC 1230000 ml 77685-001-11**

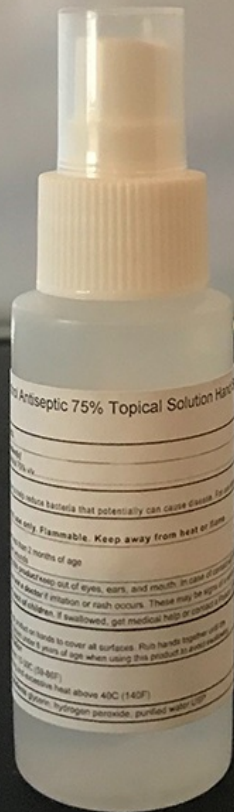
1230000 ml 77685-001-11



**2oz, 60ml spray bottle**

**77685-001-01**

77685-001-01



70% Antiseptic 75% Topical Solution

Flammable. Keep away from heat or flame.

Keep out of reach of children.

For external use only. Do not use on broken skin or mucous membranes.

Contains hydrogen peroxide, purified water.

**4 oz/ 120 ml spray bottle**

120 ml 77685-001-02



**6 oz / 180ml spray bottle**  
**77685-001-03**

180 ml 77685-001-03





**Isopropyl Alcohol Antiseptic**  
**75% Topical solution**  
**Hand Sanitizer Non-sterile**

CCIDOM

Net Content: 100 mL (3.38 FL OZ)

Contains 70% Isopropyl Alcohol (70% v/v).

Helps to help reduce bacteria that potentially can cause disease. For use on skin only. Flammable. Keep away from heat or flame.

Not for use on children under 2 months of age.

Keep this product away from eyes, ears, and mouth. In case of contact with eyes, flush with water. If irritation or rash occurs, these may be signs of a sensitive skin reaction. If irritation or rash occurs, these may be signs of a sensitive skin reaction. If irritation or rash occurs, these may be signs of a sensitive skin reaction.

Use on hands to cover all surfaces. Rub hands together until dry. Not for use on children under 6 years of age when using this product to avoid swallowing.

Store at 20°C (68-86°F). Do not store in areas where the maximum heat above 40°C (104°F).

Ingredients: Isopropyl alcohol, hydrogen peroxide, purified water.

CCIDOM CONSULTANTS, INC.  
1710-5511 CA 92880 USA  
www.ccidom.com

Batch # 02500  
Net Content

**8 oz / 240 ml spray bottle**  
**77685-001-04**

240 ml 77685-001-04



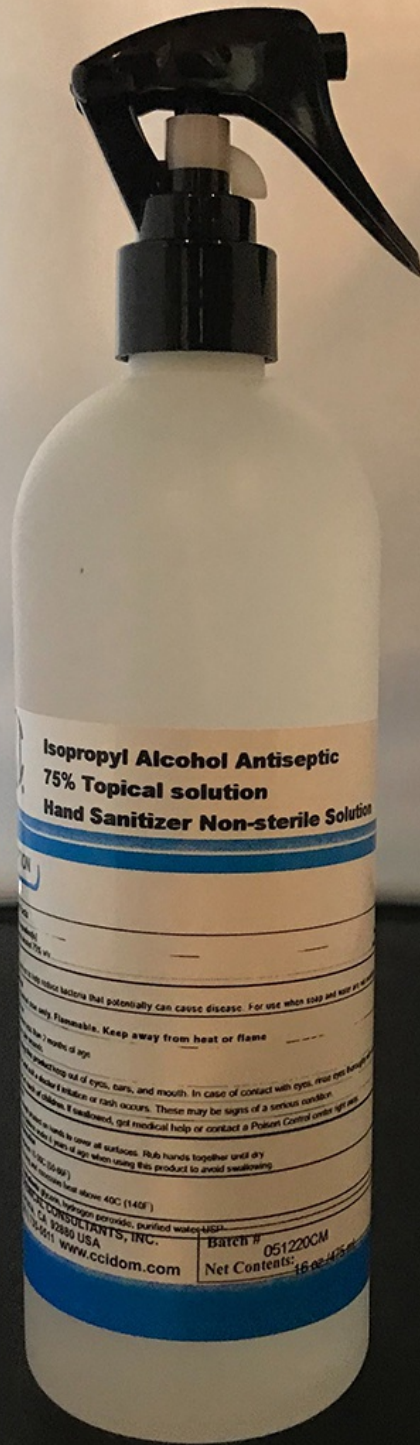
**Isopropyl Alcohol Antiseptic  
75% Topical solution  
Hand Sanitizer Non-sterile Solution**

...to reduce bacteria that potentially can cause disease. For use which keep the surface  
...Flammable. Keep away from heat or flame  
...months of age  
...out of eyes, ears, and mouth. In case of contact with eyes, flush with water  
...rash occurs. These may be signs of a serious condition.  
...get medical help or contact a Poison Control center.

...above 40C (140F)  
...hydrogen peroxide, purified water, USP  
**CONSULTANTS, INC.** Batch # 050420  
USA Net Contents: 240 mL  
www.ccidom.com

**475 ml / 16 oz spray bottle**  
**77685-001-05**

475 ml 77685-001-05



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

www.ccidom.com

Keep away from heat or flame

Flammable. Keep away from heat or flame

Keep out of eyes, ears, and mouth. In case of contact with eyes, flush with water for 15 minutes. If irritation or rash occurs, these may be signs of a serious condition. If symptoms persist, get medical help or contact a Poison Control center for advice.

Use on hands to cover all surfaces. Rub hands together until dry.

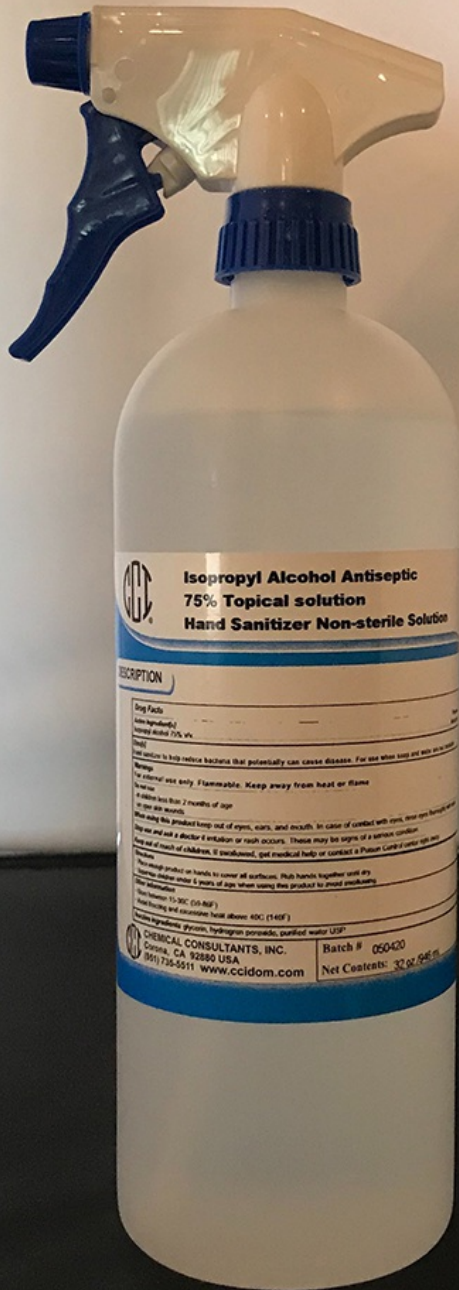
Batch # 051220CM

Net Contents: 16.0e-475 ml

www.ccidom.com

**946 ml / 32oz spray bottle**  
**77685-001-06**

946 ml 77685-001-06



**CC** **Isopropyl Alcohol Antiseptic**  
**75% Topical solution**  
**Hand Sanitizer Non-sterile Solution**

**DESCRIPTION**

**Drug Facts**  
Active ingredient(s)  
Isopropyl alcohol 70% w/v

**Warnings**  
For external use only. Flammable. Keep away from heat or flame.  
Do not use if you are pregnant or breastfeeding.  
Do not use if you are allergic to any of the ingredients.  
Do not use if you have a history of seizures.  
Do not use if you have a history of alcoholism.  
Do not use if you have a history of drug abuse.  
Do not use if you have a history of mental illness.  
Do not use if you have a history of heart disease.  
Do not use if you have a history of high blood pressure.  
Do not use if you have a history of diabetes.  
Do not use if you have a history of kidney disease.  
Do not use if you have a history of liver disease.  
Do not use if you have a history of stomach ulcers.  
Do not use if you have a history of asthma.  
Do not use if you have a history of allergies.  
Do not use if you have a history of skin conditions.  
Do not use if you have a history of eye conditions.  
Do not use if you have a history of ear conditions.  
Do not use if you have a history of nose conditions.  
Do not use if you have a history of throat conditions.  
Do not use if you have a history of mouth conditions.  
Do not use if you have a history of skin conditions.  
Do not use if you have a history of eye conditions.  
Do not use if you have a history of ear conditions.  
Do not use if you have a history of nose conditions.  
Do not use if you have a history of throat conditions.  
Do not use if you have a history of mouth conditions.

**Directions**  
Spray on hands to cover all surfaces. Rub hands together until dry.  
Do not use on children under 6 years of age when using this product for insect control.

**Other information**  
Keep between 15-30°C (59-86°F)  
Store in a cool, dry place.  
Keep away from heat and open flame.  
Keep away from children.  
Keep away from pets.  
Keep away from food and drink.  
Keep away from clothing.  
Keep away from electrical equipment.  
Keep away from flammable materials.  
Keep away from oxidizing materials.  
Keep away from acids.  
Keep away from bases.  
Keep away from poisons.  
Keep away from irritants.  
Keep away from corrosives.  
Keep away from toxic substances.  
Keep away from radioactive materials.  
Keep away from nuclear materials.  
Keep away from explosives.  
Keep away from fire.  
Keep away from lightning.  
Keep away from earthquakes.  
Keep away from tsunamis.  
Keep away from hurricanes.  
Keep away from typhoons.  
Keep away from cyclones.  
Keep away from storms.  
Keep away from rain.  
Keep away from snow.  
Keep away from ice.  
Keep away from frost.  
Keep away from hail.  
Keep away from sleet.  
Keep away from wind.  
Keep away from sun.  
Keep away from moon.  
Keep away from stars.  
Keep away from planets.  
Keep away from galaxies.  
Keep away from the universe.

**Chemical Consultants, Inc.**  
Corona, CA 92680 USA  
(951) 735-5511 www.ccidom.com

Batch # 050420  
Net Contents: 32 oz (946 mL)

**3785 ml / 128 oz jug**  
**77685-001-07**

3785 ml 77685-001-07





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

**DESCRIPTION**

**Drug Facts**

**Active ingredient(s)**  
Isopropyl alcohol 70% v/v

**Warnings**  
Read directions to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  
For external use only. Flammable. Keep away from heat or flame.

**Directions**  
• In children less than 2 months of age  
• on open skin wounds

**Other information**  
• When using this product/keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.  
• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.  
• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Contains ingredients:** glycerin, hydroxypropyl carbonyl water 100%



CHEMICAL CONSULTANTS, INC.  
Corona, CA 92880 USA  
(951) 735-5511 www.ccidom.com

Batch # 041620  
Net Contents: 1 Gal./3785 mL

**18900 ml 640 oz container**

**77685-001-08**

18900 ml 77685-001-08



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

**DESCRIPTION**

<b>Drug Facts</b>	
Active ingredient(s) Isopropyl Alcohol 75% v/v	Pharmaceutical Antiseptic
<b>Indications</b>	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not possible.
<b>Warnings</b>	For external use only. Flammable. Keep away from heat or flame. Do not use: - on children less than 2 months of age - on open skin wounds.
<b>Directions</b>	When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water. Stop use and seek 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.
<b>Other information</b>	Place a single packet on hands to cover all surfaces. Rub hands together until dry. Flammable (liquids under 1 year of age when using this product to avoid suffocation).
<b>Other information</b>	Other information: - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)
Contains isopropyl alcohol, fragrance, essential oils, purified water USP.	


CCC CHEMICAL CONSULTANTS, INC.  
Corona, CA 92880 USA  
(951) 735-5511 www.ccidom.com

Batch # 030218CG  
Net Contents: 5 Gal/18.9 mL

**208000 ml / 7040 oz drum**  
**77685-001-09**

208000 ml 77685-001-09

DIBASIC ES

 **Isopropyl Alcohol Antiseptic**  
**70% Topical solution**  
**Hand Sanitizer Non-sterile Solution**

**DESCRIPTION**

Drug Facts	Warnings
<b>Directions:</b> Use as directed. Apply to clean, dry skin. Rub hands together for 20 seconds. Avoid contact with eyes, nose, and mouth. Do not use if you are allergic to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients.	<b>Warnings:</b> Do not use if you are allergic to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients. Do not use if you have a known hypersensitivity to any of the ingredients.

**Directions:**  
Use as directed.  
Apply to clean, dry skin.  
Rub hands together for 20 seconds.  
Avoid contact with eyes, nose, and mouth.  
Do not use if you are allergic to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.

**Warnings:**  
Do not use if you are allergic to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.  
Do not use if you have a known hypersensitivity to any of the ingredients.

**Other information:**  
Keep this and all medications out of the reach of children.  
This product is not intended to be used as a disinfectant.  
This product is not intended to be used as a disinfectant.  
This product is not intended to be used as a disinfectant.

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G&S CHEMICALS, INC.  
SANTA ANA, CA 92705 USA  
951-233-2222 www.gandgs.com**

**Item # 00000000  
Net Content: 55 GAL (208 L)**

**1040000 ml 35,200 oz ibc**  
**77685-001-10**

1040000ml 77685-001-10



# HAND SANITIZER

isopropyl alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77685-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77685-001-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77685-001-02	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77685-001-03	180 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77685-001-04	240 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77685-001-05	475 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77685-001-06	946 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77685-001-07	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
8	NDC:77685-001-08	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
9	NDC:77685-001-09	208000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
10	NDC:77685-001-10	1040000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
11	NDC:77685-001-11	1230000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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** - Chemical Consultants Inc (161549829)

**Establishment**

Name	Address	ID/FEI	Business Operations
Chemical Consultants Inc		16 1549829	manufacture(77685-001) , label(77685-001) , pack(77685-001)

Revised: 5/2020

Chemical Consultants Inc