# PURITY- is opropyl alcohol liquid Vision Chemical Systems

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.

-----

### **Hand Sanitizer**

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 - 4 FL OZ

118.29 mL NDC: 76789-010-01



Isopropyl Alcohol Antiseptic 75% Topical Solution

# Hand Sanitizer

Non-sterile Solution

118.29 mL (4 FL OZ)



Drug Facts

Active ingredient[s]

Purpose

Isopropyl alcohol 75% v/v.

.. Antiseptio

## Use[s]

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 medica help or contact a Poison Control Center right away.

## Directions

S

 $\infty$ 

 $\infty$ 

 $\infty$ 

- 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

Questions? 1-888-827-4968

Manufactured by: Vision Chemical Systems Inc.

Aurora, CO 80011 886-427-4968 ● 303-371-7342
© 2020 Vision Chemical Systems Inc. All Rights Reserved.

Made in the USA

Package Label - 6 FL OZ

177.44 mL NDC: 76789-010-02



# Hand Sanitizer

Non-sterile Solution

177.44 mL (6 FL OZ)



# Drug Facts

# Active ingredient[s]

Isopropyl alcohol 75% v/v.

## Purpose

. Antiseptic

### Usels

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

S

 $\infty$ 

 $\infty$ 

 $\infty$ 

- 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

Questions? 1-888-827-4968

Manufactured by: Vision Chemical Systems Inc.
Aurora, CO 80011 888-427-4968 ● 303-371-7342
© 2020 Vision Chemical Systems Inc. All Rights Reserved.
Made in the USA

Pachage Label - 8 FL OZ

236.59 mL NDC: 76789-010-03



# Hand Sanitizer

Non-sterile Solution

236.59 mL (8 FL OZ)



# Drug Facts

# Active ingredient[s]

Isopropyl alcohol 75% v/v.

## Purpose

. Antiseptic

### Usels

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

S

 $\infty$ 

 $\infty$ 

 $\infty$ 

- 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

Questions? 1-888-827-4968

Manufactured by: Vision Chemical Systems Inc.
Aurora, CO 80011 888-427-4968 ● 303-371-7342
© 2020 Vision Chemical Systems Inc. All Rights Reserved.
Made in the USA

Package Label - 1 Gallon

3785.41 mL NDC: 76789-010-04



# **Hand Sanitizer**

Non-sterile Solution

3785.41 mL (128 US/EU FL OZ) 1 U.S. GALLON



1-888-VCS-4-YOU



Active ingredient[s]

Purpose

Isopropyl alcohol 75% v/v

Antiseptic

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.

- 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

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

### 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

Questions? 1-888-427-4968

Manufactured by: Vision Chemical Systems Inc.

Aurora, CO 80011 888-427-4968 • 303-371-7342 © 2020 Vision Chemical Systems Inc. All Rights Reserved.

Made in the USA

Package Label - 5 Gallon

18927 mL NDC: 76789-010-06



# **Hand Sanitizer**

Non-sterile Solution

18927 mL (640 US/EU FL OZ) 5 U.S. GALLONS



1-888-VCS-4-YOU



Active ingredient[s]

Purpose

Isopropyl alcohol 75% v/v

Antiseptic

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.

- 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

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

### 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

Questions? 1-888-427-4968

Manufactured by: Vision Chemical Systems Inc.

Aurora, CO 80011 888-427-4968 • 303-371-7342 © 2020 Vision Chemical Systems Inc. All Rights Reserved.

Made in the USA

Package Label - 55 Gallon Drum

208198 mL NDC: 76789-010-07



**Hand Sanitizer** Non-sterile Solution

208198 mL (7040 US/EU FL OZ) 55 U.S. GALLONS



1-888-VCS-4-YOU



Active ingredient[s]

Purpose

Isopropyl alcohol 75% v/v

Antiseptic

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.

- 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

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

### 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

Questions? 1-888-427-4968

Manufactured by: Vision Chemical Systems Inc.

Aurora, CO 80011 888-427-4968 • 303-371-7342 © 2020 Vision Chemical Systems Inc. All Rights Reserved.

Made in the USA

**Package Label - Wipes** 



# **Hand Sanitizer**

Wipes

Non-sterile Solution 888 mL (30 US/EU FL OZ)



## Drug Facts

Active ingredient[s]

Purpose Antiseptic

Isopropyl alcohol 75% v/v

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

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)
- Store between 15-30C (59-86F)
   Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide,

Questions? 1-888-427-4968

Manufactured by: Vision Chemical Systems Inc. Aurora, CO 80011 888-427-4968 • 303-371-7342 © 2020 Vision Chemical Systems Inc. All Rights Reserved.

Made in the USA

# GOING BEYOND THE

888 mL NDC: 76789-010-05

# **PURITY**

isopropyl alcohol liquid

Product	Information
IIouuct	IIIIOI IIIUUIOII

Product Type HUMAN OTC DRUG NDC:76789-010 Item Code (Source)

TOPICAL **Route of Administration** 

# **Active Ingredient/Active Moiety**

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

T4	Ingredients
inactive	Ing redients

inditive ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		

# WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76789-010-01	118.29 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:76789-010- 02	177.44 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:76789-010- 03	236.59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
4	NDC:76789-010- 04	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	04/30/2020	
5	NDC:76789-010- 06	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/30/2020	
6	NDC:76789-010- 07	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/30/2020	
7	NDC:76789-010- 05	888 mL in 1 CANISTER; Type 0: Not a Combination Product	04/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

# Labeler - Vision Chemical Systems (143308000)

# Registrant - Vision Chemical Systems (143308000)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vision Chemical Systems		143308000	manufacture(76789-010)		

Revised: 5/2020 Vision Chemical Systems