

**HAND SANITIZER- alcohol liquid**  
**CHARLES JACQUIN ET CIE, 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. 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.

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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)

**1000ml NDC 77690-919-19**

## **Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Alcohol 80%.....	Antiseptic

**Use** as a hand sanitizer to help reduce bacteria on the skin.

**Warnings** For external use only.  
**Flammable. Keep away from fire or flame.**

### **When using this product**

- Avoid contact with eyes and eye area. If contact occurs, flush thoroughly with water.
- Keep away from lips and mouth.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. Do not use on children less than 2 months of age.

### **Directions**

- Apply a palmful of alcohol - based hand rub and cover all surfaces of the hands. Rub hands until dry. Supervise children in the use of this product.

### **Other information**

- Store below 110° F( 43°C)

**Inactive Ingredients:** glycerin, hydrogen peroxide, water.



1 Liter

LX01219B

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Alcohol 80%.....	Antiseptic

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**Directions**

- Apply a palmful of alcohol - based hand rub and cover all surfaces of the hands. Rub hands until dry. Supervise children in the use of this product.

**Other information**

- Store below 110° F( 43°C)

**Inactive Ingredients:** glycerin, hydrogen peroxide, purified water.

		375ml
0	84380 01218	1 LX012188

200ml Glass Bottle NDC 77690-919-12 and 200ml Plastic Bottle NDC 77690-919-16

**Drug Facts**

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Alcohol 80%.....	Antiseptic

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Inactive ingredients

1000 ml NDC 77690-919-19

LX01219F (04/24/20)

**JACQUIN'S**

ET CIE

**HAND  
SANITIZER**

(Alcohol Antiseptic 80% Topical)

**FOR EXTERNAL USE ONLY**  
WHO RECOMMENDED FORMULATION

MADE AND BOTTLED BY  
*Charles Jacquín et Cie., Co.*  
PHILADELPHIA, PA  
1000 mL

LX01219F

→  
PRESS WEB DIRECTION - UNWIND 3

BLK

## **Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Alcohol 80%.....	Antiseptic

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**Flammable. Keep away from fire or flame.**

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1 Liter

LX01219B

**JACQUIN'S**



**HAND  
SANITIZER**

(Alcohol Antiseptic 80% Topical)

**FOR EXTERNAL USE ONLY**

WHO RECOMMENDED FORMULATION

MADE AND BOTTLED BY

*Charles Jacquin et Cie, Co.*

PHILADELPHIA, PA

375 mL

LX01218F



**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Alcohol 80%.....	Antiseptic

**Use** as a hand sanitizer to help reduce bacteria on the skin.

**Warnings** For external use only.  
**Flammable. Keep away from fire or flame.**

**When using this product**

- Avoid contact with eyes and eye area. If contact occurs, flush thoroughly with water.
- Keep away from lips and mouth.

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**Directions**

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**Inactive Ingredients:** glycerin, hydrogen peroxide, purified water.



0 84380 01218 1 375ml LX012188

200 ml glass bottle NDC 77690-919-12 and 200 ml plastic bottle NDC 77690-919-16

**JACQUIN'S**



**HAND  
SANITIZER**

**(Alcohol Antiseptic 80% Topical)**

**FOR EXTERNAL USE ONLY**  
WHO RECOMMENDED FORMULATION


MADE AND BOTTLED BY

*Charles Jacquin et Cie, Co.*

PHILADELPHIA, PA

200 mL

LX01216F

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Alcohol 80%.....	Antiseptic
<b>Use</b> as a hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings</b> For external use only. Flammable. Keep away from fire or flame.	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>• Avoid contact with eyes and eye area. If contact occurs, flush thoroughly with water.</li> <li>• Keep away from lips and mouth.</li> </ul>	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Do not use on children less than 2 months of age.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Apply a palmful of alcohol - based hand rub and cover all surfaces of the hands. Rub hands until dry. Supervise children in the use of this product.</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>• Store below 110° F(43°C)</li> </ul>	
<b>Inactive Ingredients:</b> glycerin, hydrogen peroxide, purified water.	
	
200mL	
0 84380 01216 7 LX01216B	

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77690-919
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77690-919-19	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77690-919-18	375 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77690-919-12	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77690-919-16	200 mL in 1 BOTTLE; 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** - CHARLES JACQUIN ET CIE, INC. (002293918)

## Establishment

Name	Address	ID/FEI	Business Operations
CHARLES JACQUIN ET CIE, INC.		002293918	manufacture(77690-919)

Revised: 5/2020

CHARLES JACQUIN ET CIE, INC.