#### HAND SANITIZER- alcohol gel Pacifica Chemical 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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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

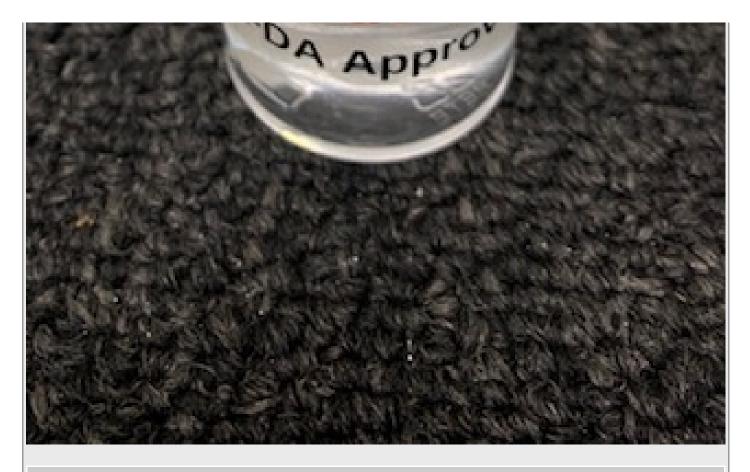


208198 mL NDC:76943-081-55

HAND SANITIZER

Product Informat	ion							
Product Type		HUMAN OTC DRUG Item Co			de (Source)		NDC:76943-081	
Route of Administrat	tion	TOPICAL						
Active Ingredient	/Active Moie	ety						
Ingredient Name					Basis of Strength		Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					ALCOHOL		80 mL ir	100 mL
Inactive Ingredie	nts							
Ingredient Name						Strength		
GLYCERIN (UNII: PDC6A3C0OX)								
(	JAJCOOAJ					1.45 mL in 10	0 mL	
		0 AN9 V)				1.45 mL in 10 0.125 mL in 1		
HYDRO GEN PERO XID	E (UNII: BBX06	0 AN9 V)						
HYDRO GEN PERO XID	E (UNII: BBX06	0 AN9 V)						
HYDROGEN PEROXID WATER (UNII: 059QF0	DE (UNII: BBX06 KO0R)	0 AN9 V)						
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte	DE (UNII: BBX06 KO0R)	0 AN9 V)						
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color	DE (UNII: BBX06 KO0R)	0 AN9 V)	Score					
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape	DE (UNII: BBX06 KO0R)	0 AN9 V)	Size					
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape Flavor	DE (UNII: BBX06 KO0R)	0 AN9 V)		e				
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape	DE (UNII: BBX06 KO0R)	0 AN9 V)	Size	2				
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape Flavor	DE (UNII: BBX06 KO0R)	0 AN9 V)	Size	e				
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape Flavor Contains	DE (UNII: BBX06 KO0R)	0 AN9 V)	Size	2				
HYDROGEN PEROXID WATER (UNII: 059QF0 Product Characte Color Shape Flavor	E (UNII: BBX06 KOOR)	0 AN9 V) Package Desc	Size Imprint Codo				00 mL	





# **Marketing Information**

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

Labeler - Pacifica Chemical Inc. (017309758)

Registrant - Pacifica Chemical Inc. (017309758)

## Establishment

Name	Address	ID/FEI	Business Operations
Pacifica Chemical Inc		017309758	manufacture(76943-081)

Revised: 10/2020

Pacifica Chemical Inc.