

## **GEL HAND SANITIZER- isopropyl alcohol gel**

### **Classic Coatings 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.*

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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.

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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

## Package Label - Principal Display Panel

Classic Hand Sanitizer is a no-rinse hand sanitizer and contains emollients to moisturize and soothe the skin. Formulated to be fragrance-free, dye-free and acceptable for use in sensitive environments such as hospitals, food processors, and other service establishments. Classic Hand Sanitizer contains at least 75% of isopropyl alcohol and meets Food & Drug Administration guidelines.

**WARNING:** FOR EXTERNAL USE ONLY. FLAMMABLE LIQUID AND VAPOR. KEEP AWAY FROM FIRE, OPEN FLAME, HOT SURFACES, SMOKING, HEAT & SPARKS. KEEP CONTAINER TIGHTLY CLOSED.

**KEEP OUT OF REACH OF CHILDREN:** IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

**AVOID EYE CONTACT:** IN CASE OF CONTACT, FLUSH THOROUGHLY WITH WATER. DO NOT INHALE OR INGEST. AVOID CONTACT WITH BROKEN SKIN. DISCONTINUE USE IF IRRITATION OR REDNESS DEVELOPS. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS CONSULT A DOCTOR.





# HAND SANITIZER

## GEL

**Kills 99.9%**  
*of harmful germs and bacteria*



**75%IPA**

**6 fl oz - (177ml)**

Active Ingredients:  
Isopropyl Alcohol 75%

Inactive ingredients: Water, Glycerin & Carbomer

**DIRECTIONS:** Place solution on hands and rub into skin until dry.

**APPLY TO HANDS**



**RUB HANDS TOGETHER UNTIL DRY**



**DO NOT USE FOR CHILDREN UNDER 2 YEARS OLD. FOR CHILDREN UNDER 6, USE ONLY UNDER ADULT SUPERVISION. STORE AT A TEMPERATURE BELOW 100F (37C)**

Manufactured by  
Classic Coatings Systems  
Corona, Ca.  
Tech Support:  
(714) 720-8954

**B#201404**

HEALTH HAZARD	0	HAZARD RATING
FLAMMABILITY	3	LEAST.....0
INFLAMMABLE		SLIGHT.....1
		MODERATE.....2
PHYSICAL HAZARD	0	HEAVY.....3
PELIGRO FÍSICO		EXTREME.....4

3785 mL NDC: 75816-175-

06

## GEL HAND SANITIZER

isopropyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75816-275
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75816-275-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75816-275-27	1040988 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/20/2020	
3	NDC:75816-275-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/20/2020	
4	NDC:75816-275-06	177 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	
5	NDC:75816-275-32	946 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	
6	NDC:75816-275-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/20/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	04/20/2020	

**Labeler** - Classic Coatings Systems (133106232)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Classic Coatings Systems		133106232	manufacture(75816-275)