

## **STAY SAFE C19 HAND SANITIZER- alcohol gel**

### **STAY SAFE C19**

*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.*

-----

### **Stay Safe C19 Hand Sanitizer**

#### **DRUG FACTS**

##### ***Active ingredient(s)***

Alcohol 70% v/v

##### ***Purpose***

Antiseptic

##### ***Use(s)***

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

##### ***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 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

##### ***Inactive ingredients***

glycerin, hydrogen peroxide, purified water USP

## Package Labeling:236ml

**STAY SAFE C19**



**HAND SANITIZER**

Manufactured in Mexico  
www.staysafec19.com

4575 Dean Martin Drive  
Las Vegas, Nevada, USA.

Alcohol Antiseptic 70%  
(WHO Formula)  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution  
Kills 99.99% of germs\*

**8 FL OZ (236 mL)**

DRUG FACTS	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
● in children less than 2 months of age ● on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
● 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.	
<b>Other information</b>	
● Store between 15-30°C (59-86°F)	
● Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

## Package Labeling:473ml

**STAY SAFE C19**



**HAND SANITIZER**

Manufactured in Mexico  
www.staysafec19.com

4575 Dean Martin Drive  
Las Vegas, Nevada, USA.

Alcohol Antiseptic 70%  
(WHO Formula)  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution  
Kills 99.99% of germs\*

**16 FL OZ (473 mL)**

DRUG FACTS	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
● in children less than 2 months of age ● on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
● 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.	
<b>Other information</b>	
● Store between 15-30°C (59-86°F)	
● Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

## Package Labeling:4L

# STAY SAFE C19



## HAND SANITIZER

Manufactured in Mexico  
www.staysafec19.com

4575 Dean Martin Drive  
Las Vegas, Nevada, USA.

Alcohol Antiseptic 70%  
(WHO Formula)  
Topical Solution

Antiseptic Hand Rub  
Non-sterile Solution  
Kills 99.99% of germs\*

1 gallon  
(135 FL OZ, 4 L)

### DRUG FACTS

Active ingredient(s)	Purpose
Alcohol 70% v/v.....	Antiseptic
<b>Use(s)</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> ● in children less than 2 months of age ● on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ● 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.	
<b>Other information</b> ● Store between 15-30°C (59-86°F) ● Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

## STAY SAFE C19 HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78842-000
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78842-000-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
2	NDC:78842-000-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
3	NDC:78842-000-03	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

OTC monograph not final	part333E	06/08/2020	
-------------------------	----------	------------	--

## **Labeler** - STAY SAFE C19 (117526387)

Revised: 6/2020

STAY SAFE C19