

HAND SANITIZER- alcohol gel
Fulfilment, S.A. de C.V.

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.

Active Ingredient(s)

Alcohol 70% 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, water, carbomer, Triethanolamine

Package Label - Principal Display Panel

5 Gallon NDC: 77483-050-01

GELCOHOL
FOR A WORLD WITHOUT GERMS

Hand Sanitizer

70% Alcohol formula

SOFT WITH YOUR HANDS

Protection
for your skin

Antibacterial **With moisturizers**

KILLS 99.99% OF MOST ILLNESS CAUSING GERMS

0% Triclosan Parabens
Sticky feeling
Fragrance

5 GALLONS (18.93 L)

GELCOHOL
FOR A WORLD WITHOUT GERMS

Hand Sanitizer

Drug Facts	Purpose
Active Ingredient Ethyl Alcohol 70%.....	Antiseptic
Use(s) • For handwashing to decrease bacteria on the skin • For use when soap and water are not available. • Recommended for repeated use.	
Warnings Flammable. Keep away from fire and flame For external use only 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	
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 59°-86°F (15°-30°C). • Avoid freezing and excessive heat above 104°F (40°C). May discolor certain fabrics	
Inactive ingredients Aqua, Carbomer, Triethanolamine, Glycerin.	

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MANUFACTURED BY:
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CUAUHTÉMOC, CIUDAD DE MEXICO,
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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77483-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77483-050-01	18927 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Fulfilment, S.A. de C.V. (815113642)

Registrant - Fulfilment, S.A. de C.V. (815113642)

Establishment

Name	Address	ID/FEI	Business Operations
Fulfilment, S.A. de C.V.		815113642	manufacture(77483-050)

Revised: 7/2020

Fulfilment, S.A. de C.V.