

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.

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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)

Inactive ingredients

Water, glycerin, Carbomer, Triethanolamine



Hand Sanitizer

70% Alcohol formula

SOFT WITH YOUR HANDS



Antibacterial

Protection
for your skin



With moisturizers

KILLS
99.99%
OF MOST ILLNESS
CAUSING GERMS

0.0% Triclosan Parabens

0%

Sticky feeling Fragrance

8.45 FL OZ (250 ML)



Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

Purpose

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.



MANUFACTURED BY:
FULFILMENT SA DE CV
PASEO DE LA REFORMA 195
PISO 6 INT 602, CUAUHTÉMOC,
CUAUHTÉMOC, CIUDAD DE MÉXICO.
MADE IN MEXICO

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77483-250
Route of Administration	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
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0K00R)	
TRIETHANOLAMINE HYDRIDIIDE (UNII: DT98IT03JK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77483-250-01	250 mL in 1 BOTTLE, PUMP; 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(77483-250)

Revised: 5/2020

Fulfilment, S.A. de C.V.