

HAND SANITIZER- alcohol gel

SanitizeNow 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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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product:

- Alcohol (ethanol) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Sterile distilled water or boiled cold water.
- Hydrogen Peroxide
- Glycerin
- Propylene Glycol
- Carbomer and/or Crosspolymers
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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 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
- In eyes. In case of contact, rinse eyes thoroughly with water

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

Water, Hydrogen Peroxide, Glycerin, Propylene Glycol, Carbomer and/or Crosspolymers.

Package Label - Principal Display Panel

3.79 L NDC: 74988-734-37

Drug Facts	
Active Ingredient Ethyl Alcohol 70%	Purpose Antiseptic
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 fire or flame.	
Do not use: on open skin wounds on children under the age of 2 months	
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)	
Inactive ingredients: Water, Hydrogen Peroxide, Glycerin, Propylene Glycol, Carbomer and/or Crosspolymers.	

Shield your hands from germs and infections.
Manufactured and bottled in the USA.
FDA registered.

Purrexx
High Potency Hand Sanitizer

70% Ethyl Alcohol Formula
HIGH-POTENCY FORMULA • HIGH-POTENCY FORMULA • HIGH-POTENCY FORMULA

KILLS 99.9% OF GERMS*

3.79L (1 Gal)

purrexx.com

This product is FDA Registered
NDC: 74988-734-37

- 01 Dispense hand sanitizer on your palms.
- 02 Rub hands together, palm to palm. Also apply to back of each hand.
- 03 Rub tips of hand with palm of other hand.
- 04 Cover all surfaces until hand feel dry (about 20 sec).

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74988-734
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

CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74988-734-37	3790 mL in 1 JAR; Type 0: Not a Combination Product	09/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2020	

Labeler - SanitizeNow Inc. (117475870)

Establishment

Name	Address	ID/FEI	Business Operations
SanitizeNow Inc.		117475870	manufacture(74988-734)

Revised: 9/2020

SanitizeNow Inc.