

KLEEN GEL- alcohol gel
Korea Miracle People Corporation Co., Ltd

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.

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% 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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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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Drug Facts Active Ingredient: Ethyl Alcohol 70.0% Purpose: Anti Microbial Uses: For hand washing to to kill or decrease bacteria on skin. Warnings: Flammable. Keep away from fire and flames. For external use only. Stop use and ask a doctor if Irritation and redness develop and persist Keep out of reach of children. If swallowed seek mediacaal help Directions: Wet hands thoroughly with product and allow to dry without wiping Inactive Ingredients: Polyacrylic acid, Glycerol, Triethanolamine, Water	 Beyond Nature® KLEEN GEL ® HAND SANITIZER GEL REFRESHING SCENTFREE CONTAINS 70%ETHYL ALCOHOL KILLS 99.99 % OF GERMS 1GAL / 3.78L NET CONTENTS: 1GALLON (128 OZ)	DESCRIPTION: Using KleenGel Hand Sanitizer is a convenient and gentle way to stay healthy. Perfect for frequent use. Mild formula is free of parabens, phthalates, preservatives and harsh ingredients, so it does not dry or irritate the skin. Hands feel soft, even after many uses. DIRECTION: Wet hands thoroughly with product and allow to dry without wiping. WARNINGS: Contains alcohol. KleenGel Hand Sanitizer is flammable and rags soaked in it will be flammable. Rags or garments soaked in KleenGel Hand Sanitizer should not be dried in a dryer even after being washed. KEEP FROM FREEZING. DO NOT MIX WITH ANYTHING BUT WATER. FOR INDUSTRIAL & INSTITUTIONAL USE ONLY. Distributed by Beyond Nature ® Oradell, NJ 07649, USA  8 54000 40544 6 Product of Korea  HDPE LABELS:PP
Drug Facts Active Ingredient: Ethyl Alcohol 70.0% Purpose: Anti Microbial Uses: For hand washing to to kill or decrease bacteria on skin. Warnings: Flammable. Keep away from fire and flames. For external use only. Stop use and ask a doctor if Irritation and redness develop and persist Keep out of reach of children. If swallowed seek mediacaal help Directions: Wet hands thoroughly with product and allow to dry without wiping Inactive Ingredients: Polyacrylic acid, Glycerol, Triethanolamine, Water	 Beyond Nature® KLEEN GEL ® HAND SANITIZER GEL REFRESHING SCENTFREE CONTAINS 70%ETHYL ALCOHOL KILLS 99.99 % OF GERMS 10.14 fl.oz (300mL)	DESCRIPTION: Using KleenGel Hand Sanitizer is a convenient and gentle way to stay healthy. Perfect for frequent use. Mild formula is free of parabens, phthalates, preservatives and harsh ingredients, so it does not dry or irritate the skin. Hands feel soft, even after many uses. DIRECTION: Wet hands thoroughly with product and allow to dry without wiping. WARNINGS: Contains alcohol. KleenGel Hand Sanitizer is flammable and rags soaked in it will be flammable. Rags or garments soaked in KleenGel Hand Sanitizer should not be dried in a dryer even after being washed. KEEP FROM FREEZING. DO NOT MIX WITH ANYTHING BUT WATER. FOR INDUSTRIAL & INSTITUTIONAL USE ONLY. Distributed by Beyond Nature ® Oradell, NJ 07649, USA  8 54000 40544 6 Product of Korea  PETE PUMP:OTHER LABELS:PP

3780 mL NDC: 77524-0050-1

KLEEN GEL

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77524-0050

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
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77524-0050-1	3780 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77524-0050-2	300 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 - Korea Miracle People Corporation Co., Ltd (693710617)

Registrant - Korea Miracle People Corporation Co., Ltd (693710617)

Establishment

Name	Address	ID/FEI	Business Operations
Korea Miracle People Corporation Co.,Ltd		693710617	manufacture(77524-0050)

Revised: 5/2020

Korea Miracle People Corporation Co., Ltd