MIRACLE ORIGIN HAND SANITIZER 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 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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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.

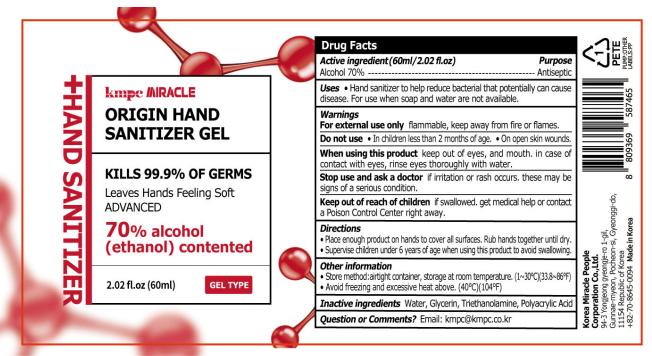
Other information

- 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





kmpe ///IRACLE

ORIGIN HAND SANITIZER GEL

KILLS 99.9% OF GERMS

Leaves Hands Feeling Soft **ADVANCED**

70% alcohol (ethanol) contented

3.38 fl.oz (100ml)

GEL TYPE

Drug Facts

Active ingredient (100ml/3.38 fl.oz) Alcohol 70% ----

Uses • Hand sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.

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Keep out of reach of children if swallowed. get medical help or contact a Poison Control Center right away.

- · 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 method: airtight container, storage at room temperature. (1~30°C)(33.8~86°F) Avoid freezing and excessive heat above. (40°C)(104°F)

Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid

Question or Comments? Email: kmpc@kmpc.co.kr



Korea Mirade People Corporation Co.,Ltd. 94-3 Yongeong gyeongje-ro 1-gil, Gunnae-myeon, Pocheon-si, Gyeonggi-do, 11154 Republic of Korea +82-70-8645-0094 Made in Korea

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Drug Facts

Active ingredient (300ml/10.14 fl.oz)

Purnose

Uses • Hand sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.

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ORIGIN HAND SANITIZER GEL

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Leaves Hands Feeling Soft ADVANCED

70% alcohol (ethanol) contented

10.14 fl.oz (300ml)



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Active ingredient (500ml/16.9 fl.oz) **Uses** • Hand sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.

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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.

Other information
• Store method: airtight container, storage at room temperature. (1~30°C)(33.8~66°F)
• Avoid freezing and excessive heat above. (40°C)(104°F)

Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid

Question or Comments? Email: kmpc@kmpc.co.kr

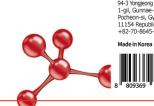
kmpe /AIRACLE HAND **ORIGIN HAND SANITIZER GEL**

KILLS 99.9% OF GERMS Leaves Hands Feeling Soft ADVANCED

70% alcohol (ethanol) contented

16.9 fl.oz (500ml)

SANITIZER



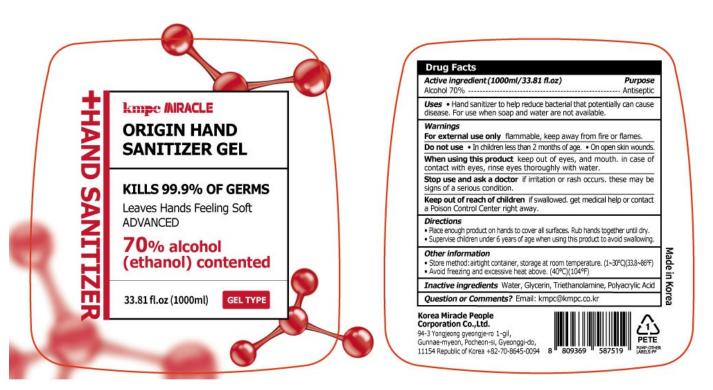


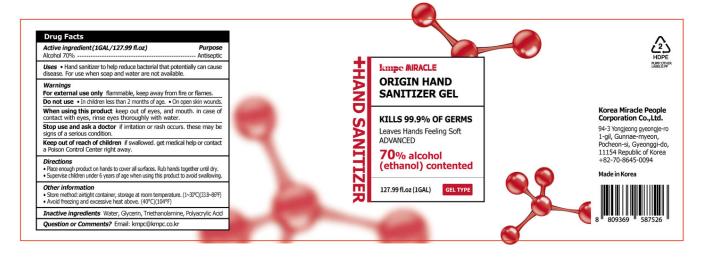
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MIRACLE ORIGIN HAND SANITIZER GEL

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77524-0020

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL			
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL			
TROLAMINE (UNII: 903K93S3TK)	0.5 mL in 100 mL			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	1	$60\ \text{mL}$ in $1\ \textsc{BOTTLE},$ PLASTIC; Type 0: Not a Combination Product	05/01/2020				
2	NDC:77524-0020- 2	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020				
3	NDC:77524-0020-3	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020				
4	NDC:77524-0020-	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020				
5	NDC:77524-0020-5	700 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020				
6	NDC:77524-0020-	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020				
7	NDC:77524-0020-7	3780 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/01/2020				

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

Establishment					
Name	Address	ID/FEI	Business Operations		
Korea Miracle People Corporation Co.,Ltd		693710617	manufacture(77524-0020)		

Revised: 6/2020

Korea Miracle People Corporation Co.,Ltd