

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

60 mL NDC: 77524-0010-1

Drug Facts	
Active ingredient (60ml/2.02 fl.oz) Alcohol 70%	Purpose Antiseptic
Uses • Hand sanitizer to help reduce bacterial 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 flames.	
Do not use • In children less than 2 months of age. • On open skin wounds.	
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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 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: kmpec@kmpec.co.kr	

70% alcohol

kmpe
MIRACLE

ORIGIN
HAND
SANITIZER
GEL

미라클 오리진 손소독제
60ml / 2.02fl.oz

Korea Miracle People Corporation Co., Ltd.
94-3 Yongjeong gyeongje-ro 1-gil,
Gummae-myeon, Pochon-si,
11154 Republic of Korea
+82-70-8645-0094 **Made in Korea**

♻️ PETE
PUMP-OUTER
LABELS/PP
8 809369 567328

Drug Facts

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

Uses • Hand sanitizer to help reduce bacterial 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 flames.

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 • Avoid freezing and excessive heat above. (40°C)(104°F)

Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid

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

70% alcohol**kmipc
MIRACLE****미라클 오리진 손소독제**
100ml / 3.38fl.oz

Korea Miracle People Corporation Co., Ltd.
 94-3 Yongjeong gyeongje-ro 1-gil,
 Gummae-myeon, Pochon-si, Gyeonggi-do,
 11154 Republic of Korea
 +82-70-8645-0094 Made in Korea

**Drug Facts**

Active ingredient (300ml/10.14 fl.oz) **Purpose**
 Alcohol 70% ----- Antiseptic

Uses • Hand sanitizer to help reduce bacterial 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 flames.

Do not use • In children less than 2 months of age. • On open skin wounds.

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 • Avoid freezing and excessive heat above. (40°C)(104°F)

Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid

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

70% alcohol**kmipc
MIRACLE****미라클 오리진 손소독제**
300ml / 10.14fl.oz

Korea Miracle People Corporation Co., Ltd.
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 Gummae-myeon, Pochon-si, Gyeonggi-do,
 11154 Republic of Korea
 +82-70-8645-0094 Made in Korea

**Drug Facts**

Active ingredient (500ml/16.9 fl.oz) **Purpose**
 Alcohol 70% ----- Antiseptic

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

Warnings

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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: kmipc@kmipc.co.kr

70% alcohol**kmipc
MIRACLE****미라클 오리진 손소독제**
500ml / 16.9fl.oz

Korea Miracle People Corporation Co., Ltd.
 94-3 Yongjeong gyeongje-ro 1-gil,
 Gummae-myeon, Pochon-si, Gyeonggi-do,
 11154 Republic of Korea
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Drug Facts	
Active ingredient (700ml/23.66 fl.oz) Alcohol 70%	Purpose Antiseptic
Uses • Hand sanitizer to help reduce bacterial 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 flames. Do not use • In children less than 2 months of age. • On open skin wounds.	
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Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid	
Question or Comments? Email: kmpc@kmpc.co.kr	

kmpe
MIRACLE

70% alcohol



미라클 오리진 손소독제
700ml / 23.66fl.oz

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



70% alcohol

kmpe
MIRACLE



미라클 오리진 손소독제
1000ml / 33.81fl.oz

Drug Facts	
Active ingredient (1000ml/33.81 fl.oz) Alcohol 70%	Purpose Antiseptic
Uses • Hand sanitizer to help reduce bacterial 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 flames. Do not use • In children less than 2 months of age. • On open skin wounds.	
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Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid	
Question or Comments? Email: kmpc@kmpc.co.kr	

Korea Miracle People Corporation Co., Ltd.

94-3 Yongjeong gyeongje-ro 1-gil,
Gunnae-myeon, Pocheon-si,
Gyeonggi-do, 11154 Republic of Korea +82-70-8645-0094



Made in Korea

Drug Facts	
Active ingredient (1GAL/127.99 fl.oz) Alcohol 70%	Purpose Antiseptic
Uses • Hand sanitizer to help reduce bacterial 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 flames. Do not use • In children less than 2 months of age. • On open skin wounds.	
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Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid	
Question or Comments? Email: kmpc@kmpc.co.kr	

kmpe
MIRACLE

70% alcohol



미라클 오리진 손소독제
1GAL / 127.99fl.oz

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



MIRACLE ORIGIN HAND SANITIZER GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77524-0010
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
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77524-0010-1	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77524-0010-2	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77524-0010-3	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77524-0010-4	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
5	NDC:77524-0010-5	700 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
6	NDC:77524-0010-6	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
7	NDC:77524-0010-7	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)

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

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 6/2020

Korea Miracle People Corporation Co.,Ltd