

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

 Korea Miracle People Corporation Co., Ltd. 94-3 Yongjeong gyeongje-ro 1-gil, Gumnae-myeon, Podchon-si, Gyeonggi-do, 11154 Republic of Korea +82-70-8645-0094 Made in Korea	 HAND SANITIZER 의약품	Drug Facts																						
		<table border="1"><thead><tr><th>Active ingredient (60ml/2.02 fl.oz)</th><th>Purpose</th></tr></thead><tbody><tr><td>Alcohol 70% -----</td><td>Antiseptic</td></tr><tr><td colspan="2">Uses • Hand sanitizer to help reduce bacterial that potentially can cause disease. For use when soap and water are not available.</td></tr><tr><td colspan="2">Warnings For external use only flammable, keep away from fire or flames.</td></tr><tr><td colspan="2">Do not use • In children less than 2 months of age. • On open skin wounds.</td></tr><tr><td colspan="2">When using this product keep out of eyes, and mouth. in case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. these may be signs of a serious condition.</td></tr><tr><td colspan="2">Keep out of reach of children if swallowed. get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">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.</td></tr><tr><td colspan="2">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)</td></tr><tr><td colspan="2">Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid</td></tr><tr><td colspan="2">Question or Comments? Email: kmpc@kmpc.co.kr</td></tr></tbody></table>	Active ingredient (60ml/2.02 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.		When using this product keep out of eyes, 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 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	
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KMPC MIRACLE ORIGIN Leaves Hands Feeling Soft ADVANCED 70% ALCOHOL (ETHANOL) CONTENTED SIMPLY KILLS 99.9% OF GERMS 미라클 오리진 손소독제 60ml / 2.02 fl.oz	 8 809369 587397 																							

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Kmpc MIRACLE



HAND SANITIZER

의약외품

KMPC MIRACLE ORIGIN
 Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

100ml / 3.38 fl.oz



8 809369 587403



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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HAND SANITIZER

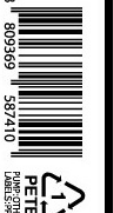
의약외품

KMPC MIRACLE ORIGIN
 Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

300ml / 10.14 fl.oz



8 809369 587410



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.

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HAND SANITIZER

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KMPC MIRACLE ORIGIN
 Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

500ml / 16.9 fl.oz



8 809369 587427



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

For external use only flammable, keep away from fire or flames.

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Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid

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MADE IN KOREA



8 809369 587434



PETE
PUMP-OTHER
LABELS-PP



HAND SANITIZER

의약품

KMPC MIRACLE ORIGIN
Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

700ml / 23.66 fl.oz

Drug Facts

Active ingredient (700ml/23.66 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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HAND SANITIZER


의약품

KMPC MIRACLE ORIGIN
Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

1000ml / 33.81 fl.oz



HAND SANITIZER

의약품

KMPC MIRACLE ORIGIN
Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제


1000ml / 33.81 fl.oz

Drug Facts


Active ingredient (1000ml/33.81 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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8 809369 587441



PETE
PUMP-OTHER
LABELS-PP

Made in Korea

kmprc MIRACLE

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Gumnae-myeon, Pocheon-si,
Gyeonggi-do, Republic of Korea
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MADE IN KOREA



8 809369 587438



HDPE
PUMP-OTHER
LABELS-PP



HAND SANITIZER

의약품

KMPC MIRACLE ORIGIN
Leaves Hands Feeling Soft ADVANCED
70% ALCOHOL (ETHANOL) CONTENTED

SIMPLY KILLS 99.9% OF GERMS

미라클 오리진 손소독제

1GAL / 127.99 fl.oz

Drug Facts

Active ingredient (1GAL/127.99 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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Inactive ingredients Water, Glycerin, Triethanolamine, Polyacrylic Acid	
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MIRACLE ORIGIN HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77524-0030
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
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	28.5 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:77524-0030-1	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77524-0030-2	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77524-0030-3	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77524-0030-4	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
5	NDC:77524-0030-5	700 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
6	NDC:77524-0030-6	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	
7	NDC:77524-0030-7	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
Korea Miracle People Corporation Co.,Ltd		693710617	manufacture(77524-0030)

Revised: 6/2020

Korea Miracle People Corporation Co.,Ltd