HAND SANITIZER GEL- ethyl alcohol gel SPIRIT PHARMACEUTICALS LLC

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.

HAND SANITIZER gel

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- hand sanitizer to help reduce bacteria on the skin that potentially can cause disease
- recommend for repeated use

Warnings

For external use only. Flammable. Keep away from heat and 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 appears and lasts. 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.
- Children under 6 years of age should be supervised when using this product

Other Information

- Store between 15°-30°C (59°86°F)
- Avoid freezing and excessive heat above 40°C (104°F)
- may discolor certain fabrics or surfaces

Inactive ingredients

carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl acetate, triethanolamine, water

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

HAND-SANITIZER GEL

EFFECTIVELY KILLS 99.9% OF THE

MOST COMMON GERMS/ BACTERIA

70%

ALCOHOL CONTENT

WITH

VITAMIN E & MOISTURIZERS

PLEASANT FRAGRANCE

STAY PROTECTED

65 ml / 75 ml / 150 ml / 250 ml / 500 ml / 1000 ml (REFILL PACK) / 2000 ml (REFILL PACK) / 4000 ml (REFILL PACK)

MODD

Active ingredient

Purpose

Ethyl Alcohol 70% v/v.....

...Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on the skin that potentially can cause disease ■ recommend for repeated use

Warnings

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Do not use in children less than 2 months of age

■ on open skin wounds
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Questions or comments? 1-888-333-9792

Manufactured by: APL P.O.Box 7771, Ajman, UAE Under License From MODD PERFUMES & COSMETICS 10 Cameron Road, Seven Kings London, IG3 8LA United Kingdom MADE IN U.A.E. 6



64822-1











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EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS**

PLEASANT FRAGRANCE

STAY PROTECTED

2.19 FL.0Z. (65 ml)





EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS** PLEASANT FRAGRANCE

STAY PROTECTED

2.53 FL.OZ. (75ml)





HAND SANITIZER GEL

Active ingredient Ethyl Alcohol 70% v/v..

Purpose .Antiseptic

Uses hand sanitizer to help reduce bacteria on the skin that potentially can cause disease recommend for repeated use

Warnings
For external use only. Flammable. Keep away from heat and 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 appears and lasts. These may

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Directions ■ Place enough product on hands to cover all surfaces.
Rub hands together until dry. ■ Children under 6 years of age should be supervised when using this product
Other information ■ Store between 15*-30*C (59*-86*F)
■ Avoid freezing and excessive heat above 40*C (104*F)

may discolor certain fabrics or surfaces

Inactive ingredients carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl acetate, triethanolamine, water

Questions or comments? 1-888-333-9792

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United Kingdom

Distributed By:

Spirit Pharmaceuticals, LLC Ronkonkoma, NY 11779







EFFECTIVELY KILLS 99.9% OF THE MOST COMMON **GERMS / BACTERIA**

70% ALCOHOL CONTENT WITH VITAMIN E & MOISTURIZERS

PLEASANT FRAGRANCE

STAY PROTECTED

5.07 FL.OZ. (150 ml)



Active ingredient

Ethyl Alcohol 70% v/v......

Purpose .Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on the skin that potentially can cause disease

recommend for repeated use

Warnings

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Do not use in children less than 2 months of age

on open skin wounds

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Other information

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- Avoid freezing and excessive heat above 40°C (104°F)
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Questions or comments? 1-888-333-9792

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64825-2





EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS**

PLEASANT FRAGRANCE

STAY PROTECTED

8.45 FL.OZ. (250 ml)



Drug Facts

Active ingredient Ethyl Alcohol 70% v/v...

Purpose ..Antiseptic

Uses anitizer to help reduce bacteria on the skin that potentially can cause disease recommend for repeated use

Warnings For external use only. Flammable. Keep away from heat

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.

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Inactive ingredients carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl acetate, triethanolamine, water

Questions or comments? 1-888-333-9792

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MODD PERFUMES & COSMETICS

10 Cameron Road, Seven Kings London, IG3 8LA United Kingdom





MADE IN U.A.E.

64826-9



Drug Facts

Active ingredient Ethyl Alcohol 70% v/v.... Purpose ..Antiseptic

USES hand sanitizer to help reduce bacteria on the skin that potentially can cause disease recommend for repeated

Warnings

For external use only. Flammable. Keep away from heat and

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 appears and lasts. 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

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(59°-86°F) ■ Avoid freezing and excessive heat above 40°C (104°F) ■ may discolor certain fabrics or surfaces

Inactive ingredients carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl acetate, triethanolamine, water

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Spirit Pharmaceuticals, LLC Ronkonkoma, NY 11779







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HAND SANITIZER GEL

EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS**

PLEASANT FRAGRANCE

STAY PROTECTED

16.9 FL.0Z. (500 ml)





EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS**

PLEASANT FRAGRANCE

STAY PROTECTED

33.8 FL.0Z. (1000 ml)





HAND SANITIZER GEL

Active ingredient Purpose Ethyl Alcohol 70% v/vAntiseptic	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Uses ■ hand sanitizer to help reduce bacteria on the skin that potentially can cause disease ■ recommend for repeated use	Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry. ■ Children under 6 years of age should be	
Warnings	supervised when using this product	
For external use only. Flammable. Keep away from heat and flame.	Other information Store between 15°-30°C (59°-86°F) Avoid freezing and excessive heat above 40°C (104°F) may discolor certain fabrics or surfaces	
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 thorough- ly with water. Stop use and ask a doctor if irritation or 	Inactive ingredients carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl acetate, triethanolamine, water	
rash appears and lasts. These may be signs of a serious condition.	Questions or comments? 1-888-333-9792	

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HAND SANITIZER GEL

EFFECTIVELY KILLS 99.9% OF THE MOST COMMON GERMS / BACTERIA

70% ALCOHOL CONTENT WITH **VITAMIN E & MOISTURIZERS**

PLEASANT FRAGRANCE

STAY PROTECTED

67.6 FL.OZ. (2000ml)







HAND SANITIZER GEL

	Drug Facts	Drug Facts (continued)	
	Active ingredient Purpose Ethyl Alcohol 70% v/vAntiseptic	Keep out of reach of children. If swallowed get medical help or contact a Poison Contro Center right away.	
	Uses ■ hand sanitizer to help reduce bacteria on the skin that potentially can cause disease ■ recommend for repeated use	Directions ■ Place enough product on hands to cover all surfaces. Rub hands together until dry ■ Children under 6 years of age should be	
	Warnings For external use only. Flammable. Keep away from heat and flame.	supervised when using this product	
		Other information Store between 15°-30°C (59°-86°F)	
	Do not use ■ in children less than 2 months of age ■ on open skin wounds	Avoid freezing and excessive heat above 40°C (104°F) may discolor certain fabrics or surfaces	
	When using this product keep out of eyes, ears and mouth, in case	Inactive ingredients	
	of contact with eyes, rinse eyes thorough- ly with water.	carbomer, fragrance, glycerin, hydrogen peroxide, propylene glycol, tocopheryl	
	Stop use and ask a doctor if irritation or rash appears and lasts. These may be signs of a serious condition.	acetate, triethanolamine, water	
		Questions or comments? 1-888-333-9792	









HAND SANITIZER GEL

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4075
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 HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 903K93S3TK)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210- 4075-6	65 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
2	NDC:68210- 4075-3	75 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
3	NDC:68210- 4075-1	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
4	NDC:68210- 4075-2	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
5	NDC:68210- 4075-5	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	
6	NDC:68210- 4075-8	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/08/2020	
7	NDC:68210- 4075-7	2000 mL in 1 PACKAGE; Type 0: Not a Combination Product	06/08/2020	
8	NDC:68210- 4075-4	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2022 SPIRIT PHARMACEUTICALS LLC