HAND SANITIZER- ethyl alcohol gel
Charles and Associates, 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.

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):

a. Alcohol (71%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (0.5% v/v).
c. Carbomer (8.0% v/v).
d. Trolamine (1.0% v/v).
e. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria on the skin that potentially can cause sickness, recommended for repeated use.

Warnings

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

Avoid contact with eyes, ears, and mouth. If contact does occur, flush with water.

Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help, or contact poison control center right away.

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Directions

- Apply a small amount to palms, rubbing briskly to cover both hands until dry - repeat as necessary.
- Supervise children under 6 years with the use of this product. Do not use on infants.

Other information

- Store at room temperature
- May discolor certain fabrics

- Harmful to wood finishes and plastics

Inactive ingredients

Deminerialized water, Carbopol 960, Triethanolamine, Glycerin

Package Label - Principal Display Panel

1 gallon / 128 fl oz (3.79 liters) NDC: 78336-070-37

16.9 fl oz (500 ml) NDC: 78336-070-16

8.45 fl oz (250 ml) NDC: 78336-070-08

4.06 fl oz (120 ml) NDC: 78336-070-04

2.03 fl oz (60 ml) NDC: 78336-070-02

1 fl oz (30 ml) NDC: 78336-070-01

1 liter (1000ml) 33.8 fl oz NDC: 78336-070-10

Drug Facts
Active Ingredient **Purpose** Ethyl Alcohol 70% v/v ..... Antiseptic
Uses ● Hand sanitizer to help reduce bacteria on the skin that potentially can cause sickness.
Warnings **For external use only.**
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Directions ● Apply a small amount to palms, rubbing briskly to cover both hands until dry – repeat as necessary. **Supervise children under 6** yrs. Don not use on infants.
Other Information ● Store at room temperature. May discolor certain fabrics. Harmful to wood.
Inactive Ingredients ● Demineralized water, Carbopol 960, Triethanolamine, Glycerin
Questions/Comments? +1.480.444.2522
Distributed by Charles & Associates, 105 S. State St. #609, Orem, Utah 84058, USA Made in Mexico

Hand Sanitizer

Moisturizing Gel

Kills 99% of Germs

1 fl oz (30 ml)

3 78336 07001 2

Drug Facts	
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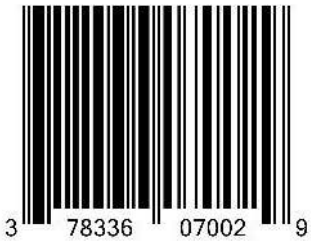
Hand Sanitizer

Moisturizing Gel

Kills 99% of Germs

2.03 fl oz (60 ml)



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HAND SANITIZER

Kills 99% of Germs

Moisturizing Gel

Other Information

● Store at room temperature
May discolor certain fabrics
Harmful to wood finishes and plastics

Inactive Ingredients

● Demineralized water, Carbopol 960, Triethanolamine, Glycerin

Questions/Comments? +1.480.444.2522

Distributed by Charles & Associates,
105 S. State St. #609,
Orem, Utah 84058, USA Made in Mexico

3 78336 07004 3

4.06 fl oz (120 ml)

HAND SANITIZER

Kills 99% of Germs

Moisturizing Gel

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Active Ingredient **Purpose**
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Questions/Comments? +1.480.444.2522

Distributed by Charles & Associates,
105 S. State St. #609,
Orem, Utah 84058, USA Made in Mexico

3 78336 07008 1

8.45 fl oz (250 ml)

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78336-170
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	8 mL in 100 mL
WATER (UNII: 059QF0KO0R)	19.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78336-170-37	3785 mL in 1 JUG; Type 0: Not a Combination Product	07/01/2020	
2	NDC:78336-170-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
3	NDC:78336-170-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
4	NDC:78336-170-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
5	NDC:78336-170-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
6	NDC:78336-170-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78336-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

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2	NDC:78336-070-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2020	
3	NDC:78336-070-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2020	
4	NDC:78336-070-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2020	
5	NDC:78336-070-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2020	
6	NDC:78336-070-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	
7	NDC:78336-070-10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/12/2020	

Labeler - Charles and Associates, LLC (120983354)

Revised: 7/2020 Charles and Associates, LLC