MAGIC SOFT HAND SANITIZER- ethyl alcohol gel
UNIVERSAL MANUFACTURING CORP.

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.

Magic Soft Hand Sanitizer

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)

Ethyl 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.

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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Deionized water, Acrylates/C10-30 alkyl acrylate crosspolymer, Triethanolamine, EDTA.

Package Label - Principal Display Panel

148 mL NDC: 77855-200-15

Magic Soft

Hand Sanitizer

ELIMINATE MORE GERMS

10 FL OZ (296 mL)

Drug Facts

Active Ingredient — **Purpose**

Ethyl Alcohol 65% v/v ---- Antimicrobial

Uses • Hand Sanitizer to help reduce bacteria on the skin that could cause disease • Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and last.

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

Drug Facts (cont.)

Directions • Place enough product in your palm to thoroughly cover your hands. • Rub hands together briskly until dry. • Children under 6 years of age should be supervised when using this product.

Other Information

• Store below 110°F (43°C) • May discolor certain fabrics or surfaces.

Inactive ingredients Water (Agua), Tert Butanol, Glicerine, Propylene Glycol, EHE Cellulose.

Questions or comments

Call 1-800-222-1222 Monday through Friday 8:00 AM to 5:00 PM.
Code: D10101

7 04300 91032 7

Distributed by:
Universal Manufacturing Corp.
MADE IN USA

296 mL NDC: 77855-200-20

Drug Facts (cont.)

Directions • Place enough product in your palm to thoroughly cover your hands. • Rub hands together briskly until dry. • Children under 6 years of age should be supervised when using this product.

Other Information

• Store below 110°F (43°C) • May discolor certain fabrics or surfaces.

Inactive ingredients Water (Agua), Tert Butanol, Glicerine, Propylene Glycol, EHE Cellulose.

Questions or comments

Call 1-800-222-1222 Monday through Friday 8:00 AM to 5:00 PM.
Code: D10101

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Magic Soft

Hand Sanitizer

ELIMINATE MORE GERMS

32 FL OZ (946mL)

Drug Facts

Active Ingredient — **Purpose**

Ethyl Alcohol 65% v/v ---- Antimicrobial

Uses • Hand Sanitizer to help reduce bacteria on the skin that could cause disease • Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and last.

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

Distributed by:
Universal Manufacturing Corp.
MADE IN USA

946 mL NDC: 77855-200-30

3.8 L NDC: 77855-200-30

MAGIC SOFT HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77855-200
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**
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.15 mL in 100 mL
HYDROXYETHYL ETHYLCELLULOSE (UNII: ZDN57Z154K)	1.25 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.5 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77855-200-15	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
2	NDC:77855-200-20	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
3	NDC:77855-200-30	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

4	NDC:77855-200-40	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

Labeler - UNIVERSAL MANUFACTURING CORP. (014030808)

Revised: 5/2020 UNIVERSAL MANUFACTURING CORP.