

MAJESTIC INSTANT HAND SANITIZER- ethyl alcohol gel
Global Cosmetics (China) Company Limited

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.

Majestic Instant Hand Sanitizer

Drug Facts

Active Ingredients

Ethyl Alcohol 75% v/v

Purpose

Antimicrobial

Uses: Hand Sanitizer to help reduce bacteria on skin.

Warnings: Flammable. Keep away from fire or flame. For external use only.

Do not use

- In Children less than 2 months of age
- on open skin

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.

Directions:

- Place enough product on hands to cover all surfaces. Rub hand together until dry
- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information:

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

Inactive Ingredients: Aqua, Glycerin, Carbomer, Triethanolamine, Tocopheryl Acetate, Centella Asiatica Extract, Aloe Barbadensis Leaf Juice, Citric Acid.

Brought to you by clinicians with your well-being in mind.

Kills 99.9% of germs

Contains 75% Alcohol
 Suitable for hand cleaning

Cleans and disinfects

Distributed by
 Majestic Group LLC
 5006 Herzel Place
 Beltsville Maryland 20705

Email: sales@majesticssuppliers.com

Website: www.majesticssuppliers.com



Phone: +1 (301) 792-2121

Made in China

Packaging



DRUG FACTS LABEL

Drug Facts	Purpose
Active Ingredients Ethyl Alcohol 75% v/v.....	Antimicrobial
Uses: Hand Sanitizer to help reduce bacteria on skin.	
Warnings: Flammable. Keep away from fire or flame. For external use only. Do not use	
<ul style="list-style-type: none"> • In Children less than 2 months of age • on open skin 	 
<p>When using this product Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water</p> <p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p>	
Directions:	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hand together until dry • Supervise children under 6 years of age when using this product to avoid swallowing 	
Other Information:	
<ul style="list-style-type: none"> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive Ingredients: Aqua, Glycerin, Carbomer, Triethanolamine, Tocopheryl Acetate, Centella Asiatica Extract, Aloe Barbadensis Leaf Juice, Citric Acid.	

MAJESTIC INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71650-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CENTELLA ASIATICA WHOLE (UNII: 7M867G6T1U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71650-008-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
2	NDC:71650-008-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
3	NDC:71650-008-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
4	NDC:71650-008-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
5	NDC:71650-008-05	5000 mL in 1 CAN; Type 0: Not a Combination Product	05/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/08/2020	

Labeler - Global Cosmetics (China) Company Limited (527852739)**Establishment**

Name	Address	ID/FEI	Business Operations
Global Cosmetics (China) Company Limited		527852739	manufacture(71650-008)

Revised: 5/2020

Global Cosmetics (China) Company Limited