HAND SANITIZING GEL- alcohol gel
Alpha Aromatics

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 Sanitizing Gel 62% (v/v)

The hand sanitizer is manufactured in accordance with the recommendations in 21 CFR Part 333 for alcohol based topical antimicrobial OTC products for human use.

a. Alcohol(Ethanol) 62% (v/v).
b. Sorbitol 0.6% (v/v).
c. Gylcerin 0.6% (v/v).
d. PEG-27 copolymer 0.375% (v/v)
e. Triethanol 0.7% (v/v)
f. 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 80% 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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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

203000 mL NDC: 75009-162-01

ALCOHOL ANTISEPTIC 62% TOPICAL GEL Hand Sanitizer Non-Sterile Solution 203 L/180 kg	**Drug Facts** **Active ingredient[s]** — **Purpose** Alcohol 62% (v/v) ..... Antiseptic **Use[s]** Hand Sanitizer to help reduce bacteria that potentially can cause disease. **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 out children.** If swallowed, get medical help or contact Poison Control Center right away. **Directions** • Place a dime sized amount in hand. Rub hands 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** purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine

868300 mL NDC: 75009-162-02

ALCOHOL ANTISEPTIC 62% TOPICAL GEL Hand Sanitizer Non-Sterile Solution 203 L/180 kg	**Drug Facts** **Active ingredient[s]** — **Purpose** Alcohol 62% (v/v) ..... Antiseptic **Use[s]** Hand Sanitizer to help reduce bacteria that potentially can cause disease. **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 out children.** If swallowed, get medical help or contact Poison Control Center right away. **Directions** • Place a dime sized amount in hand. Rub hands 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** purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine

HAND SANITIZING GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75009-162
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TROLAMINE (UNII: 9O3K93S3TK)	0.7 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.6 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	0.375 mL in 100 mL
SORBITOL SOLUTION (UNII: 8KW3E207O2)	0.6 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75009-162-01	203000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75009-162-02	868300 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Alpha Aromatics (041723545)

Establishment

Name	Address	ID/FEI	Business Operations
Alpha Aromatics		041723545	manufacture(75009-162)

Revised: 4/2020 Alpha Aromatics