HAND SANITIZER- 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.

Mint Hand Sanitizing Gel 62%

The hand sanitizer is manufactured using only the following ingredients:

- 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.
- g. fragrance

Active Ingredient(s)

Alcohol 62% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

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Directions

- Place a dime sized amount in hands. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

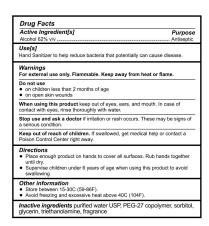
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance

Package Label - Principal Display Panel

55 gallons NDC: 75009-362-01





GHS HAZARDS: Highly flammable liquid and vapor.



PRECAUTIONS: Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. No smoking away from near/sparks/open llames/not surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/ lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial

KEEP OUT OF REACH OF CHILDREN CONSULT THE SDS FOR FURTHER INFORMATION

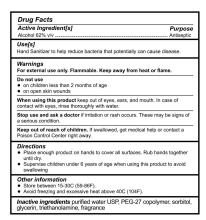


62% Alcohol Antiseptic Topical Gel **Hand Sanitizer**

55 Gallons / 208.19 liters

Non-Sterile Solution

275 gallons NDC: 75009-362-02





GHS HAZARDS: Highly flammable liquid and vapor.



🚯 DANGER 🍅



PRECAUTIONS: Obtain special instructions before use. Keep PREJAUTIONS: Obtains special instructions belorde use. Reep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventillating/ lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool

DISPOSAL: Dispose of contents/container to industrial combustion plant.

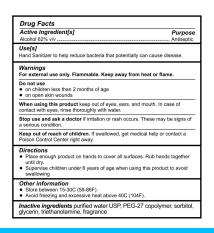
> KEEP OUT OF REACH OF CHILDREN CONSULT THE SDS FOR FURTHER INFORMATION



62% Alcohol Antiseptic Topical Gel **Hand Sanitizer**

Non-Sterile Solution

5 gallons NDC: 75009-362-03





GHS HAZARDS: Highly flammable liquid and vapor.



PRECAUTIONS: Obtain special instructions before use. Keep away from heal/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

KEEP OUT OF REACH OF CHILDREN CONSULT THE SDS FOR FURTHER INFORMATION



62% Alcohol **Antiseptic Topical Gel Hand Sanitizer**

Non-Sterile Solution

1 gallon NDC: 75009-362-04

| Active Ingredient[s] Alcohol 62% v/v | Purpos Antiseption |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Use[s] Hand Sanitizer to help reduce bacteria that potentially can caus | se disease. |
| Warnings For external use only. Flammable. Keep away from heat or | flame. |
| Do not use on children less than 2 months of age on open skin wounds | |
| When using this product keep out of eyes, ears, and mouth. contact with eyes, rinse thoroughly with water. | In case of |
| Stop use and ask a doctor if irritation or rash occurs. These ra serious condition. | may be signs of |
| Keep out of reach of children. If swallowed, get medical help Poison Control Center right away. | or contact a |
| Directions Place enough product on hands to cover all surfaces. Rub huntil dry. Supervise children under 6 years of age when using this proswallowing | |
| Other information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). | |
| Inactive ingredients purified water USP, PEG-27 copol glycerin, triethanolamine, fragrance | lymer, sorbitol, |



GHS HAZARDS: Highly flammable liquid and vapor.

DANGER (M)

PRECAUTIONS: Obtain special instructions before use. Keep away from heal/sparks/open flames/hot surfaces. No smoking, keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/ lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

KEEP OUT OF REACH OF CHILDREN CONSULT THE SDS FOR FURTHER INFORMATION



62% Alcohol Antiseptic Topical Gel Hand Sanitizer

Non-Sterile Solution

1 quart NDC: 75009-362-05

| Active Ingredient[s] Alcohol 62% v/v | Purpose Antiseptic |
|------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Use[s] Hand Sanitizer to help reduce bacteria that potent | ially can cause disease. |
| Warnings For external use only. Flammable. Keep away f | rom heat or flame. |
| Do not use on children less than 2 months of age on open skin wounds | |
| When using this product keep out of eyes, ears, contact with eyes, rinse thoroughly with water. | and mouth. In case of |
| Stop use and ask a doctor if irritation or rash occ a serious condition. | curs. These may be signs of |
| Keep out of reach of children. If swallowed, get Poison Control Center right away. | medical help or contact a |
| Pirections Place enough product on hands to cover all sur until dry. Supervise children under 6 years of age when swallowing | |
| Other information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (| 104F). |
| Inactive ingredients purified water USP, PE | G-27 copolymer, sorbitol, |



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



PRECAUTIONS: Obtain special instructions before use. Keep away from heal/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

KEEP OUT OF REACH OF CHILDREN CONSULT THE SDS FOR FURTHER INFORMATION



62% Alcohol **Antiseptic Topical Gel Hand Sanitizer**

Non-Sterile Solution

HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75009-362

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 62 mL in 100 mL |

| Inactive Ingredients | | | |
|----------------------------------------------------------------------------------|-------------------|--|--|
| Ingredient Name | Strength | | |
| MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N) | 4.45 mL in 100 mL | | |
| ACRYLIC ACID/ISO PHO RO NE DIISO CYANATE/PEG-27 CO POLYMER (UNII: R0 R8 I3X29 J) | 0.75 mL in 100 mL | | |
| TROLAMINE (UNII: 903K93S3TK) | 0.7 mL in 100 mL | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 0.6 mL in 100 mL | | |
| SORBITOL SOLUTION (UNII: 8KW3E207O2) | 0.6 mL in 100 mL | | |
| WATER (UNII: 059QF0KO0R) | | | |

| l | Packaging | | | | |
|---|-----------|----------------------|------------------------------------------------------------------------------------------|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 | NDC:75009- 362-01 | 208190 mL in 1 DRUM; Type 0: Not a Combination Product | 03/30/2020 | |
| | 2 | NDC:75009- 362-02 | 1040980 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 03/30/2020 | |
| П | | NIDG FEOOD | | | |

| 362-03 | 18920 mL in 1 PAIL; Type 0: Not a Combination Product | 03/30/2020 |
|----------------------------------------------------------------------------|-------------------------------------------------------|------------|
| 4 NDC:75009- 362-04 3780 mL in 1 JUG; Type 0: Not a Combination Product | | 03/30/2020 |
| 5 NDC:750 | 946 mL in 1 BOTTLE; 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(75009-362) |

Revised: 5/2020 Alpha Aromatics