HAND SANITIZER- alcohol liquid 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 Sanitizer 80%

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)

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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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

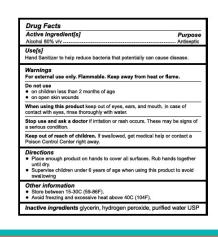
glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

55 gallons NDC: 75009-080-01



275 gallons NDC: 75009-080-02





GHS HAZARDS: Highly flammable liquid and vapor, Harmful if swallowed. May cause cancer.



PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Wear protective gloves/eye protection.

FIRST AID: If swallowed: Call a poison center/doctor if

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

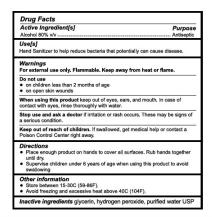
CONSULT THE SDS FOR FURTHER INFORMATION



80% Alcohol **Hand Sanitizer** Topical Solution 275 Gallons / 1,040.98 liters

Antiseptic Hand Rub Non-Sterile Solution

5 gallons NDC: 75009-080-03





GHS HAZARDS: Highly flammable liquid and vapor, Harmful if swallowed. May cause cancer.







PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Wear protective gloves/eye protection.

FIRST AID: If swallowed: Call a poison center/doctor if

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION



80% Alcohol Hand Sanitizer Topical Solution

Antiseptic Hand Rub Non-Sterile Solution

1 gallon NDC: 75009-080-04

Active Ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentia	lly can cause disease.
<i>Warnings</i> For external use only. Flammable. Keep away fro	om 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, a contact with eyes, rinse thoroughly with water.	and mouth. In case of
Stop use and ask a doctor if irritation or rash occu a serious condition.	rs. These may be signs of
Keep out of reach of children. If swallowed, get m Poison Control Center right away.	nedical help or contact a
Directions Place enough product on hands to cover all surfauntil dry. Supervise children under 6 years of age when us swallowing	
Other information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (1	04F).
Inactive ingredients glycerin, hydrogen pero	xide, purified water USP



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





PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Wear protective gloves/eye protection.

FIRST AID: If swallowed: Call a poison center/doctor if you feel unwell.

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

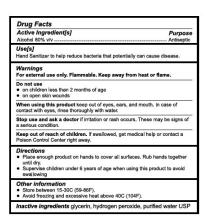
CONSULT THE SDS FOR FURTHER INFORMATION



80% Alcohol **Hand Sanitizer** Topical Solution

Antiseptic Hand Rub Non-Sterile Solution

1 quart NDC: 75009-080-05





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





PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Wear protective gloves/eye protection.

FIRST AID: If swallowed: Call a poison center/doctor if

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

DISPOSAL: Dispose of contents/container in accordance with local regulations

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION



80% Alcohol **Hand Sanitizer** Topical Solution

1 Quart / .946 liters

Antiseptic Hand Rub Non-Sterile Solution

HAND SANITIZER

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG NDC:75009-080 Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	T . I' . NT	n to de	G1	
ı	Ingredient Name	Basis of Strength	Strength	
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75009- 080-01	214745.88 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020		
2	NDC:75009- 080-02	9 18 6 3 5 . 17 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020		
3	NDC:75009- 080-03	18920 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020		
4	NDC:75009- 080-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020		
5	NDC:75009- 080-05	946 mL in 1 BOTTLE, PLASTIC; 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(75009-080)		

Revised: 5/2020 Alpha Aromatics