# 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.

-----

#### Lavender Hand Sanitizer 80%

The hand sanitizer is manufactured using only the following ingredients:

- 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.
- e. Fragrance

## 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.

## 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

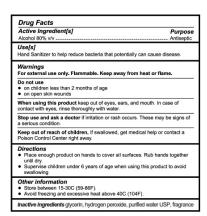
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP, fragrance

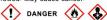
### Package Label - Principal Display Panel

55 gallons NDC: 75009-680-01





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



PRECAUTIONS: Obtain special instructions before PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hort 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

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

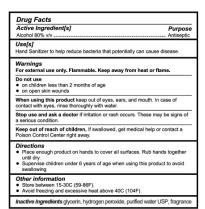
CONSULT THE SDS FOR FURTHER INFORMATION



80% Alcohol **Hand Sanitizer** Topical Solution

**Antiseptic Hand Rub** 

#### 275 gallons NDC:75009-680-02





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







PRECAUTIONS: Obtain special instructions before PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hort 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 protection 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.

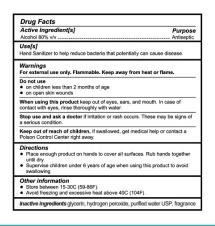
KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION



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

**Antiseptic Hand Rub Non-Sterile Solution** 





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 gallon NDC:75009-680-04

Active Ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially	can cause disease.
Warnings For external use only. Flammable. Keep away fron	n 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 contact with eyes, rinse thoroughly with water.	d mouth. In case of
Stop use and ask a doctor if irritation or rash occurs a serious condition.	. These may be signs of
Keep out of reach of children. If swallowed, get med Poison Control Center right away.	dical help or contact a
Directions Place enough product on hands to cover all surfacuntil dry. Supervise children under 6 years of age when usin swallowing	
Other information  Store between 15-30C (59-86F).  Avoid freezing and excessive heat above 40C (104)	F).
Inactive ingredients glycerin, hydrogen peroxide, puri	fled water USP, fragrance



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







PRECAUTIONS: Obtain special instructions before 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

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** 

1 quart NDC: 75009-680-05

Active Ingredient[s] Alcohol 80% v/v	PurposeAntiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potential	ly can cause disease.
Warnings For external use only. Flammable. Keep away fro	m 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.	nd mouth. In case of
Stop use and ask a doctor if irritation or rash occur a serious condition.	s. These may be signs of
Keep out of reach of children. If swallowed, get me Poison Control Center right away.	edical 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 (10	04F)



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



80% Alcohol Hand Sanitizer Topical Solution

Antiseptic Hand Rub Non-Sterile Solution

02020 ASI

### HAND SANITIZER

alcohol liquid

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:75009-680

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)ALCOHOL80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
PIPERO NAL (UNII: KE109 YAK00)	0.005 mL in 100 mL			
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.07 mL in 100 mL			
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	0.02 mL in 100 mL			
4-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 21EUM2B8UC)	0.01 mL in 100 mL			
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	0.005 mL in 100 mL			
LINALOOL, (+/-)- (UNII: D81QY6188E)	0.05 mL in 100 mL			
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540 GJV69)	0.02 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.03 mL in 100 mL			

Packaging			
# Itam Cada	Package Description	Marketing	Marketing End

#	Item Coue	rackage Description	Start Date	Date
1	NDC:75009- 680-01	208190 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75009- 680-02	1040980 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75009- 680-03	18920 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75009- 680-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75009- 680-05	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(75009-680)	

Revised: 5/2020 Alpha Aromatics