

HAND SANITIZER- alcohol liquid

Ashburn Chemical Technologies

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.

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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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

An alcohol-based liquid hand sanitizer that evaporates quickly. It is recommended for repeated use to help decrease bacteria on the skin.

DIRECTIONS

Apply a "palmful" to one hand - enough to thoroughly cover both hands. Spread on both hands including front and back of hands, thumbs and fingers. Rub hands together briskly until dry.

WARNING

H226 Flammable liquid and vapor.
H319 Causes serious eye irritation.



P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective eye protection/ face protection
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P363 Wash contaminated clothing before reuse.
P312: Call a poison center or doctor/physician if you feel unwell.
P370+P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
P305+P351 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
P338 Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P325 Keep cool
P405 Store locked up
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.



DOT SHIPPING NAME:

Ethanol Solution, 3, UN 1170, PG II FLAMMABLE LIQUID

Ashburn Chemical Technologies
7403 Wright Rd • Houston, TX 77041
(832) 399-1000

Batch#



Alcohol Antiseptic 80%
Topical Solution

- Hand Sanitizer
- Non-sterile Solution

Part# M-05025



KEEP OUT OF REACH OF CHILDREN
NET CONTENTS: 5 GALLONS

18.927 L 5 gal NDC: 74677-050-05

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74677-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74677-050-05	18927.059 mL in 1 PAIL; Type 0: Not a Combination Product	04/09/2020	
2	NDC:74677-050-55	208197.648 mL in 1 DRUM; Type 0: Not a Combination Product	04/09/2020	
3	NDC:74677-050-23	1040988.24 mL in 1 DRUM; Type 0: Not a Combination Product	04/09/2020	
4	NDC:74677-050-01	3785.412 mL in 1 JUG; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/08/2020	

Labeler - Ashburn Chemical Technologies (044454924)**Establishment**

Name	Address	ID/FEI	Business Operations
Ashburn Chemical Technologies		044454924	manufacture(74677-050)

Revised: 4/2020

Ashburn Chemical Technologies