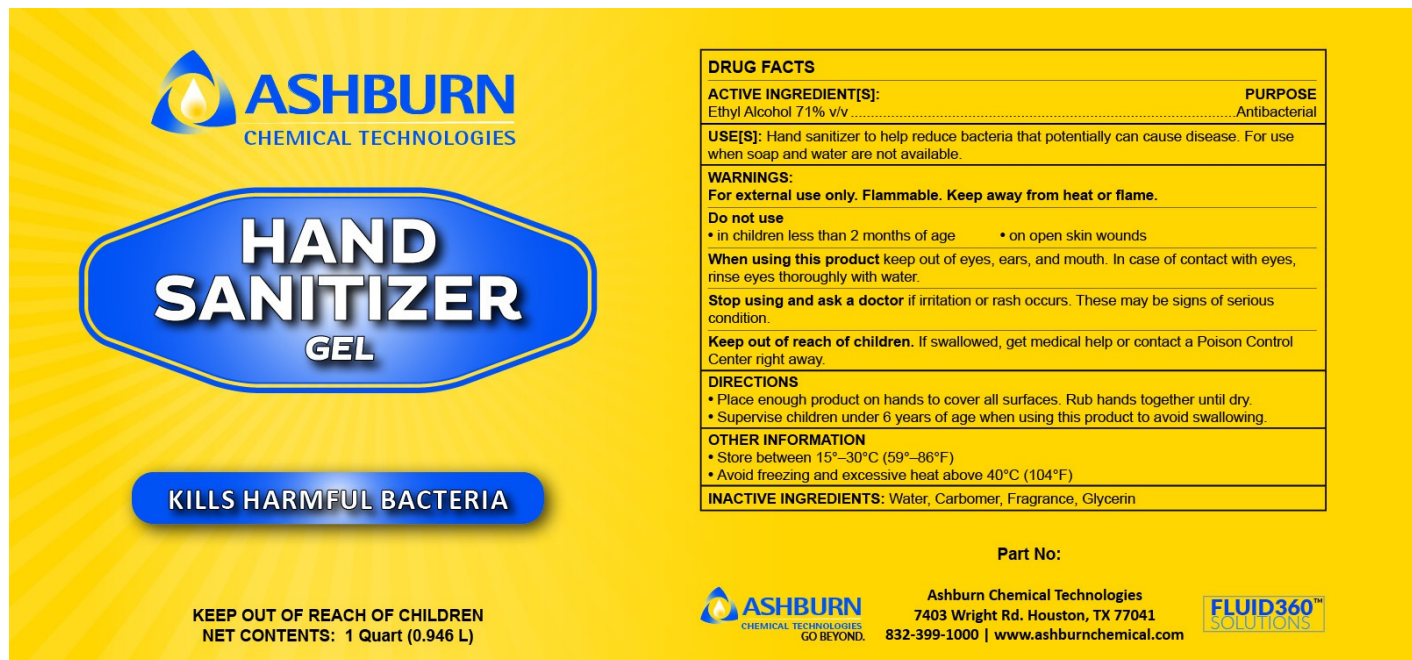


ASHBURN HAND SANITIZER GEL- hand sanitizer gel

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.

Ashburn Hand Sanitizer Gel



The image shows the front and back of a yellow Ashburn Hand Sanitizer Gel container. The front panel features the Ashburn Chemical Technologies logo at the top left, a large blue oval with 'HAND SANITIZER GEL' in white, and a blue button that says 'KILLS HARMFUL BACTERIA'. At the bottom, it says 'KEEP OUT OF REACH OF CHILDREN' and 'NET CONTENTS: 1 Quart (0.946 L)'. The back panel contains a 'DRUG FACTS' table with sections for Active Ingredient(s), Purpose, Use(s), Warnings, Directions, Other Information, and Inactive Ingredients. The Ashburn logo and Fluid360 Solutions logo are at the bottom right of the back panel.

DRUG FACTS	
ACTIVE INGREDIENT(S): Ethyl Alcohol 71% v/v	PURPOSE Antibacterial
USE(S): 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 using and ask a doctor if irritation or rash occurs. These may be signs of 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°–30°C (59°–86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
INACTIVE INGREDIENTS: Water, Carbomer, Fragrance, Glycerin	

Part No:

Ashburn Chemical Technologies
7403 Wright Rd. Houston, TX 77041
832-399-1000 | www.ashburnchemical.com

FLUID360™
SOLUTIONS

Ashburn Hand Sanitizer Gel

Ashburn hand Sanitizer Gel - 1 Qt.jpg

Ashburn Hand Sanitizer Gel - 1 Qt back.jpg

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hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74677-095
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.05 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
AMMONIUM ACRYLO YLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74677-095-15	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:74677-095-23	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
3	NDC:74677-095-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/18/2020	
4	NDC:74677-095-22	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
5	NDC:74677-095-17	208198 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Ashburn Chemical Technologies (044454924)

Registrant - Ashburn Chemical Technologies (044454924)

Establishment

Name	Address	ID/FEI	Business Operations
Ashburn Chemical Technologies		044454924	manufacture(74677-095)

Revised: 5/2020

Ashburn Chemical Technologies