

62% ALCOHOL HAND SANITIZER- hand sanitizer gel
Ultra Distributors Inc

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.

Disinfection
Sterilization
No Rinseing

Alcohol62%

Directions: Pour a sufficient amount of the liquid into the palm of your dry hands. Rub thoroughly all over hands briskly until dry. Repeat if necessary. Use without water. Use only under adult supervision.

Warnings: Highly flammable liquid and vapour. Causes serious eye irritation. May cause skin irritation. Keep away from heat, sparks, hot surfaces, fire, open flame and sources of ignition. No smoking. Keep at room temperature. Store in a well-ventilated, cool and dry place, away from direct sunlight. Do not store above 40 °C

For external use only.

Avoid contact with eyes. If in eyes, rinse immediately with clean water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Do not swallow. If swallowed, rinse mouth and seek medical advice immediately and show this label. Do not induce vomiting. Do not use on damage, inflamed or broken skin. If irritation or redness develops, discontinue use.

Keep out of the reach of babies, children & animals.

236ml store in ventilated shade and Do not store above 40 °C

Alcohol, water/eau/aqua, carbomer□triethanolamine, propylene glycol, glycerin

Front Panel and Back Panel Art



Drug Facts	
Active ingredient Ethyl alcohol 62%	Purpose Antiseptic
Uses • to decrease bacteria on the skin that could cause disease • recommended for repeated use	
Warnings For external use only; hands Flammable. Keep away from fire or flame.	
When using this product • keep out of eyes. In case of contact with eyes, flush thoroughly with water. • avoid contact with broken skin • do not inhale or ingest	
Stop use and ask a doctor if • irritation or redness develops • condition persists for more than 72 hours	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
Directions • wet hands thoroughly with product and allow to dry without wiping • for children under 6, use only under adult supervision • not recommended for infants	
Other information • do not store above 105°F • may discolor some fabrics • harmful to wood finishes and plastics	
Inactive ingredients Purified Water, Glycerin, Carbomer, Triethanolamine, Propylene Glycol	

Distributed by: Ultra Distributors inc
Somerset NJ 08873, USA
Made in China

Item No. 84648
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62% ALCOHOL HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78495-015
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	146.32 mL in 236 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78495-015-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/07/2020	

Labeler - Ultra Distributors Inc (007160073)**Establishment**

Name	Address	ID/FEI	Business Operations
Ultra Distributors		007160073	relabel(78495-015)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Home Solution Corp., LTD		679868836	manufacture(78495-015)

Revised: 12/2021

Ultra Distributors Inc