

HAND SANITIZER- gel hand sanitizer gel
State Industrial Products

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.

State Industrial F056F

Directions Apply a small amount to palm. Briskly rub, covering hands with product until dry.

Uses Hand Sanitizer to help reduce bacteria on the skin that could cause disease.

Active Ingredient Ethyl Alcohol 62% v/v

Keep out of reach of children. If swallowed, contact a physician or poison control center.

Purpose Antibacterial Agent

Inactive Ingredients Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol.

Warnings For external use only. FLAMMABLE. Keep away from heat or flame. Do not use in the eyes. If eye contact occurs, flush with water. Stop and ask a doctor if redness and irritation occur and last more than 72 hours.



KUTOL Hand Hygiene Specialists 513-527-5500 513-527-5506 fax blevenson@kutol.com KUTOL INTERNAL Approved <u>LG</u> Date <u>03/10/2020</u> Changes:	Label No. <u>LAM1463A</u> Size <u>4.5 x 3.3125</u> Unwind _____ Colors <u>PMS 3145 teal, PMS 361 green PMS 2995 blue & Black</u> Printed on _____ Formula <u>056F</u>
	Item No. (Kutol use only) <u>128281</u> Revisions: 3/6/20 - New product

Printer - please put our formula number on your proof.

Principal Label

HAND SANITIZER

gel hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64542-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CARBOMER 1342 (UNII: 809Y72KV36)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64542-056-35	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/09/2020	

Labeler - State Industrial Products (004520987)

Registrant - Kutol Products Company (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company		004236139	manufacture(64542-056)

