AFFEX CARE ULTRA HAND SANITIZER- alcohol gel
Autotrol Corporation

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.

27129 Hand Sanitizer

Ethyl Alcohol 70% v/v

Antiseptic

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Flammable. Keep away from heat or flame

For external use only.

place enough product in your palm to thoroughly cover your hands
rub hands together briskly until dry
children under 6 years of age should be supervised when using this product

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

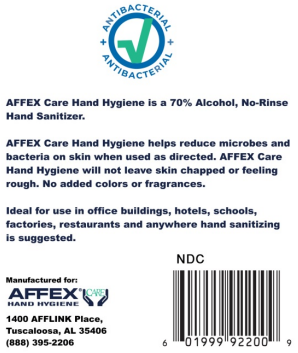
Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

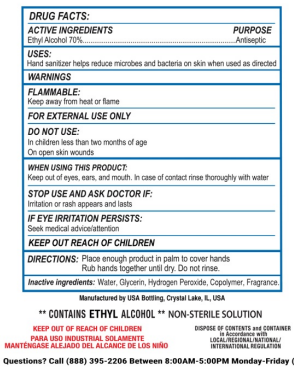
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a physician if skin irritation or rash develops.

Water, Glycerin, Carbomer, Aloe, Tocopheryl Acetate

3785 mL NDC: 79097-020-28





AFFEX CARE ULTRA HAND SANITIZER alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79097-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79097-020-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
2	NDC:79097-020-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
3	NDC:79097-020-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
4	NDC:79097-020-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
5	NDC:79097-020-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
6	NDC:79097-020-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
7	NDC:79097-020-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
8	NDC:79097-020-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
9	NDC:79097-020-75	1000000 mL in 1 TANK; Type 0: Not a Combination Product	07/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/13/2020	

Labeler - Autotrol Corporation (001755131)

Establishment

Name	Address	ID/FEI	Business Operations
Autotrol Corporation		001755131	label(79097-020) , manufacture(79097-020) , pack(79097-020)

Revised: 12/2021

Autotrol Corporation