

AFFEX CARE 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.

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 Hand Hygiene is a 70% Alcohol, No-Rinse Hand Sanitizer.

AFFEX Care Hand Hygiene helps reduce microbes and bacteria on skin when used as directed. AFFEX Care Hand Hygiene will not leave skin chapped or feeling rough. No added colors or fragrances.

Ideal for use in office buildings, hotels, schools, factories, restaurants and anywhere hand sanitizing is suggested.

Manufactured for:
AFFEX CARE
HAND HYGIENE
1400 AFLINK Place,
Tuscaloosa, AL 35406
(888) 395-2206

NDC



DRUG FACTS:	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70%	Antiseptic
USES:	
Hand sanitizer helps reduce microbes and bacteria on skin when used as directed	
WARNINGS	
FLAMMABLE:	
Keep away from heat or flame	
FOR EXTERNAL USE ONLY	
DO NOT USE:	
In children less than two months of age	
On open skin wounds	
WHEN USING THIS PRODUCT:	
Keep out of eyes, ears, and mouth. In case of contact rinse thoroughly with water.	
STOP USE AND ASK DOCTOR IF:	
Irritation or rash appears and lasts	
IF EYE IRRITATION PERSISTS:	
Seek medical advice/attention	
KEEP OUT REACH OF CHILDREN	
DIRECTIONS: Place enough product in palm to cover hands	
Rub hands together until dry. Do not rinse.	
Inactive ingredients: Water, Glycerin, Hydrogen Peroxide, Copolymer, Fragrance.	
Manufactured by USA Bottling, Crystal Lake, IL, USA	

**** CONTAINS ETHYL ALCOHOL ** NON-STERILE SOLUTION**
KEEP OUT OF REACH OF CHILDREN DISPOSE OF CONTENTS AND CONTAINER
PARA USO INDUSTRIAL SOLAMENTE EN UN CONTAINERO SEPARADO
MANTENGASE ALEJADO DEL ALCANCE DE LOS NIÑOS INTERNATIONAL REGULATORY
QUESTIONS? Call (888) 395-2206 Between 8:00AM-5:00PM Monday-Friday (CST)

AFFEX CARE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79097-023
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: 059QF0K00R)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79097-023-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
2	NDC:79097-023-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
3	NDC:79097-023-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
4	NDC:79097-023-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
5	NDC:79097-023-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
6	NDC:79097-023-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
7	NDC:79097-023-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
8	NDC:79097-023-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/2020	
9	NDC:79097-023-75	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(79097-023) , manufacture(79097-023) , pack(79097-023)

Revised: 12/2021

Autotrol Corporation