

U INSTANT HAND SANITIZER CLASSIC- ethyl alcohol gel
BIOTEK INDIA

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.

U INSTANT HAND SANITIZER

Drug Facts

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antimicrobial

Uses

Hand Sanitizer to help reduce bacteria on skin.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

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 doctor if irritation or rash appears and lasts.

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

Directions:

- Place enough Product in your palm to thoroughly spread on both hands and rub into the skin until dry.
- Children under 6 years of age should be supervised when using this product.

Other Information:

- Store below 106° F. (41°C)
- May discolor certain fabrics or surfaces

INACTIVE INGREDIENTS:

Water(Aqua), Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine.

With Vitamin E & Other Moisturizers

KILLS GERMS WITHOUT WATER

UNIVERSAL INSTANT HAND SANITIZER

Made in India

Distributed by: Universal Distribution Center
96 Distribution Boulevard • Edison, NJ 08817

Packaging

U INSTANT HAND SANITIZER CLASSIC

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73003-005
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
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C00X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73003-005-05	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
2	NDC:73003-005-04	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
3	NDC:73003-005-09	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
4	NDC:73003-005-06	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
5	NDC:73003-005-03	2 in 1 BLISTER PACK	01/01/2020	
5		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:73003-005-01	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
7	NDC:73003-005-07	350 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
8	NDC:73003-005-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
9	NDC:73003-005-08	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	
10	NDC:73003-005-10	55 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2020	

Labeler - BIOTEK INDIA (675484458)

Establishment

Name	Address	ID/FEI	Business Operations
BIOTEK INDIA		675484458	manufacture(73003-005)