ANTIBACTERIAL HAND SANITIZER- alcohol liquid Ankit LLC

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.

Active Ingredient

Alcohol 75% v/v.

Purpose

Antiseptic

Uses

Eliminate bacteria and viral matter on the skin.

Warnings

Do not use

- on children under 2 months of age
- on open wounds

When using:

Avoid contact with face. eyes. and broken skin. In case of eye contact, flush with clean water and seek medical assistance.

Stop use and contact a doctor if:

Irritation or redness occurs.

Keep out of reach of children. In case of ingestion, seek medical help or contact a Poison Control Center immediately.

Directions

- Dispense a liberal amount of product on hands, enough to coat palms and fingers and then rub until dry.
- Supervise small children to ensure proper usage and prevent ingestion.

Other information

- Store below 110°F[43°C].
- May discolor certain fabrics/surfaces.

Inactive ingredients

Water, Aloe, Carbomer, Triethanolamine.

Package Label - Principal Display Panel

i-bacteria

HYL ALCOHOL

ADE WITH SKIN NOURISHING ALOE VERA GEL

5.3Gallons/20Litres

Drug Facts

Active ingredient

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FDA# 10070117, NDC#74621-002-10

Suite 100, Boca Raton, FL 33431 FDA# 10070117 Made in China 02694

Distributed by:

Ankit, LLC

2385 NW Executive

Center Drive

ANTIBACTERIAL HAND SANITIZER

alcohol liquid

Product Information

HUMAN OTC DRUG NDC:78887-001 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
TROLAMINE (UNII: 9O3K93S3TK)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78887-001-	29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
2	NDC:78887-001- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
3	NDC:78887-001- 03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
4	NDC:78887-001- 04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
5	NDC:78887-001- 05	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
6	NDC:78887-001- 06	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
7	NDC:78887-001- 07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
8	NDC:78887-001- 08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
9	NDC:78887-001- 09	887 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
10	NDC:78887-001- 10	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
11	NDC:78887-001- 11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
12	NDC:78887-001- 12	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
13	NDC:78887-001- 13	3000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
14	NDC:78887-001- 14	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
15	NDC:78887-001- 15	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
16	NDC:78887-001- 16	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
17	NDC:78887-001- 17	7600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
18	NDC:78887-001- 18	10000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
19	NDC:78887-001- 19	11400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	
20	NDC:78887-001- 20	18900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020	

21	NDC:78887-001- 21	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020
22	NDC:78887-001- 22	37900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020
23	NDC:78887-001- 23	50000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020
24	NDC:78887-001- 24	100000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020
25	NDC:78887-001- 25	150000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020
26	NDC:78887-001- 26	200000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2020

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/13/2020		

Labeler - Ankit LLC (805718140)

Revised: 6/2020 Ankit LLC