DEFENDER COLLECTION- alcohol gel Tiger Hospitality, LLC dba A1 American

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

Ethyl Alcohol 70% v/v.

Purpose

Antiseptic

Uses

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

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

in children less than 2 months of age on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Adult supervision for children under 6 years of age when using this product to avoide swallowing.
- Not recommended for infants.

Other information

• Store between 15-30C (59-86F)

• Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, ethanolamine, polyethylene glycol, water USP.

Product Label



DEFENDER COLLECTION

alcohol gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78940-002

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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC.70040			

1	NDC: 78940- 002-01	9 mL in 1 TUBE; Type 0: Not a Combination Product	06/27/2020	
2	NDC:78940- 002-02	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
3	NDC:78940- 002-03	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
4	NDC:78940- 002-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
5	NDC:78940- 002-05	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
6	NDC:78940- 002-06	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
7	NDC:78940- 002-07	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
8	NDC:78940- 002-08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	
9	NDC:78940- 002-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/27/2020	

arketing Start Marketing End Date Date
7/2020

Labeler - Tiger Hospitality, LLC dba A1 American (021848056)

Revised: 12/2022 Tiger Hospitality, LLC dba A1 American