

**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.*

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**Active Ingredient**

Ethyl Alcohol 70% v/v.

**Purpose**

Antiseptic

**Use**

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.
- Supervise children under 6 years of age when using this product to avoid swallowing. Not recommended for infants.

**Other information**

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

**Inactive ingredients**

Water, isopropyl alcohol, carbopol, glycerin, propylene glycol, aminomethyl propanol, aloe, Vitamin E, Fragrance.

**Package Label - Principal Display Panel**

MANUFACTURED FOR:  
A1 AMERICAN  
12386 OSBORNE PLACE  
PACOIMA, CA 91331



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# HAND SANITIZER

HELPS KILL  
HARMFUL GERMS

UNSCENTED GEL  
Ethyl Alcohol Antiseptic Solution

1 GALLON (3.8 Liters)



Drug Facts	
<b>Active ingredient(s)</b> Ethyl Alcohol 70% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> - in children less than 2 months of age - on open skin wounds	
<b>When using this product keep out of eyes, ear, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b>	
<b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<b>Directions</b> - 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 avoid swallowing. Not recommended for infants.	
<b>Other information</b> - Store between 15-30C (59-86F) - Avoid Freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Water, isopropyl alcohol, carbopol, glycerin, propylene glycol, aminomethyl propanol, aloe, Vitamin E, Fragrance.	

## DEFENDER COLLECTION

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78940-004
<b>Route of Administration</b>	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)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78940-004-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
2	NDC:78940-004-02	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
3	NDC:78940-004-03	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	

4	NDC:78940-004-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
5	NDC:78940-004-05	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
6	NDC:78940-004-06	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
7	NDC:78940-004-07	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2020	
8	NDC:78940-004-08	30 mL in 1 TUBE; Type 0: Not a Combination Product	08/07/2020	
9	NDC:78940-004-09	25 mL in 1 TUBE; Type 0: Not a Combination Product	08/07/2020	
10	NDC:78940-004-10	15 mL in 1 TUBE; Type 0: Not a Combination Product	08/07/2020	
11	NDC:78940-004-11	9 mL in 1 TUBE; Type 0: Not a Combination Product	08/07/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/07/2020	

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

Revised: 11/2020

Tiger Hospitality, LLC dba A1 American