# PRIME- alcohol gel Prime Industries Usa, Inc

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 75% v/v.

## **Purpose**

Antiseptic

#### Uses

- Hand sanitizer to help decrease bacteria on the skin.
- When water, soap & towel are not available.
- Recommended for repealed use.

## Warnings

- For external use only
- Flammable. Keep away from fire or flame.
- Do not apply around eyes. Do not use in ears & mouth.
- When using this product avoid contact with eyes.
- In case of contact flush eyes with water.
- Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

#### **Directions**

- Pump as needed into your palms and thoroughly spread on both hand.
- Rub into skin until dry.

#### Other information

- Store at 20°C (88-77°F).
- May discolor fabrics.

# **Inactive ingredients**

Water, Glycerin, Aloe barbadensis leaf extract, Carbomer, Tocopheryl Acetate, Triethanolamine.

# Package Label - Principal Display Panel

60 mL



100 mL



237 mL





500 mL



## **PRIME**

alcohol gel

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79382-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 903K93S3TK)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79382-001- 01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
2	NDC:79382-001- 02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
3	NDC:79382-001- 03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
4	NDC:79382-001- 04	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
5	NDC:79382-001- 05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2020	
6	NDC:79382-001- 06	1000 mL in 1 DRUM; Type 0: Not a Combination Product	06/26/2020	
7	NDC:79382-001- 07	5000 mL in 1 DRUM; Type 0: Not a Combination Product	06/26/2020	
8	NDC:79382-001- 08	200000 mL in 1 DRUM; Type 0: Not a Combination Product	06/26/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/26/2020		

# Labeler - Prime Industries Usa, Inc (117547551)

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