

INSTANT HAND SANITIZER - ethyl alcohol gel
PrimeCare + 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.

Active Ingredient
75% Ethyl Alcohol

Purpose
Antiseptic

Uses:

- For hand washing to decrease bacteria/microorganisms on the skin that can cause diseases.
- Recommended for repeated use.

Warnings:

- ◇ For external use only. Avoid contact with broken skin.
 - ◇ Flammable, keep away from heat, flame or fire.
 - ◇ Do not use this product, in or near the eyes.
 - ◇ If eye contact, immediately rinse thoroughly with a lot of water.
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- Stop use and ask a doctor if irritation, redness, or rash develops and persists for more than 3 days.
- If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. Do not inhale or ingest.

Directions:

- ◇ Wet hands thoroughly with product
 - ◇ Rub hands together covering all surfaces until dry quickly without wiping infants
 - ◇ Not recommended for use in children under 6 years of age must be supervised
 - ◇ Do not store above 105 F or 39 C
 - ◇ May discolor some fabrics, wood finishes and plastics
- Other Information:
-

Inactive Ingredients:

Water, Aloe Barbadensis Leaf Juice, Glycerin, Propylene Glycol, Carbomer, Aminomethyl Propanol, Hamamelis Virginiana (witchhazel) Leaf Extract, Fragrance

PrimeCare +[®]

Instant Hand Sanitizer

With

Natural Moisturizing

Aloe Vera

&

Antiseptic Witch Hazel

Kills 99.99% of germs

Tough on germs Gentle on hands



Contains 8 oz (240 ml) gel



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Prime Care + Inc.
611 West Main St. Arlington, Texas
USA 76010 Phone number: 18175389147
Made in China



INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69410-0001
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINO METHYLPRO PANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HAMAMELIS VIRGINIANA LEAF WATER (UNII: 8FP93ED6H2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69410-0001-8	240 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/26/2014	

