# INSTANT HAND SANITIZER- ethyl alcohol gel BB17, 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.

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# **Active Ingredient:**

Ethyl Alcohol 62%

# **Purpose:**

Antimicrobial

### **WARNING:**

**FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.** FOR EXTERNAL USE ONLY.DO NOT USE IN THE EYES.

DISCONTINUE USE IF IRRITATION AND REDNESS DEVELOP. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS, CONSULT A DOCTOR OR PHYSICIAN.

# KEEP OUT OF REACH OF CHILDREN.

#### **Directions:**

Rub into hands until dry.

Water, Aloe barbadenis Leaf Juice, Glycerin, Propylene Glycol, Fragrance, Carbomer, Triethanolamine, FD&C Blue No.1, D&C Red No.33.

### Other Information:

Store below 110 F.

KILLS MORE THAN 99.99% OF COMMON GERMS





Note: This is the inside of a peel off label DRUG FACTS Active Ingredient: WARNING: Ethyl Alcohol 62% FLAMMABLE KEEP AWAY Purpose: Antimicrobial FROM FIRE OR FLAME. Directions: Rub into hands until dry. FOR EXTERNAL USE ONLY. DO NOT USE IN THE EYES. Other Information: Store below 110 ° F. **DISCONTINUE USE IF** IRRITATION AND REDNESS Inactive Ingredients: DEVELOP, IF CONDITION PERSISTS FOR MORE THAN Water, Aloe Barbadensis Leaf Juice, Glycerin, 72 HOURS, CONSULT A Propylene Glycol, DOCTOR OR PHYSICIAN. Fragrance, Carbomer, Triethanolamine, KEEP OUT OF REACH OF CHILDREN. FD&C Blue No.1, D&C Red No.33.

# INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53603-1039	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
TROLAMINE (UNII: 9O3K93S3TK)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:53603-1039-	29.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/27/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/27/2015	

# **Labeler** - BB17, LLC (828378294)

Revised: 9/2015 BB17, LLC