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.

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, Olive Oil, Fragrance, Carbomer, Triethanolamine, FD&C Red No.4, FD&C Yellow No.5.

Other Information:

Store below 110 F.

KILLS MORE THAN 99.99% OF COMMON GERMS

Front Label

Back Label - Peel off label





Note: This is the inside of a peel off label DRUG FACTS Active Ingredient: Ethyl Alcohol 62% Purpose: Antimicrobial WARNING: FLAMMABLE KEEP AWAY 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 Water, Aloe Barbadensis PERSISTS FOR MORE THAN Water, Aloe Barbadensis Leaf Juice, Glycerin, Propylene Glycol, Olive Oil, Fragrance, Carbomer, Triethanolamine, FD&C Red No.4, FD&C Yellow No.5. 72 HOURS, CONSULT A DOCTOR OR PHYSICIAN. KEEP OUT OF REACH OF CHILDREN.

Hang Tag





INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53603-1032

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:53603-1032- 1	29.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/21/2015	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	07/21/2015			

Labeler - BB17, LLC (828378294)

Revised: 9/2015 BB17, LLC