HAND SANITIZER GEL- 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 Blue No.1, D&C Red No.33.

Other Information:

Store below 110 F.

KILLS MORE THAN 99.99% OF COMMON GERMS





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

HAND SANITIZER GEL

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53603-1051
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)		
OLIVE OIL (UNII: 6UYK2W1W1E)		

l	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:53603-1051-1	29.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/14/2018		

Labeler - BB17, LLC (828378294)

Revised: 7/2018 BB17, LLC