

ANTI-BACTERIAL 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.

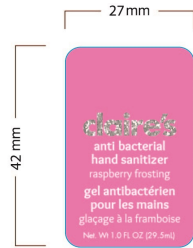
Water, Aloe barbadensis Leaf Juice, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, Tocopheryl Acetate, FD&C Red NO.4, FD&C Red NO.33.

Other Information:

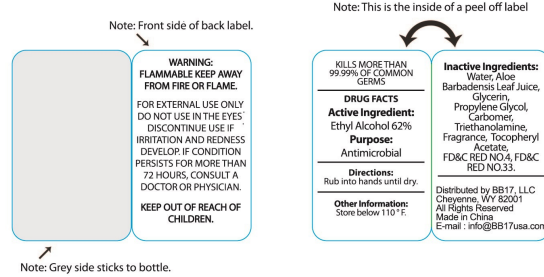
Store below 110 F.

KILLS MORE THAN 99.99% OF COMMON GERMS

Front Label



Back Label - Peel off label



ANTI-BACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53603-1022
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53603-1022-1	29.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/06/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/06/2015	

Labeler - BB17, LLC (828378294)

Revised: 4/2015

BB17, LLC