

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 Ingredients

Ethyl Alcohol 62%

Purpose

Antimicrobial

KILLS MORE THAN 99.99% OF COMMON GERMS

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.

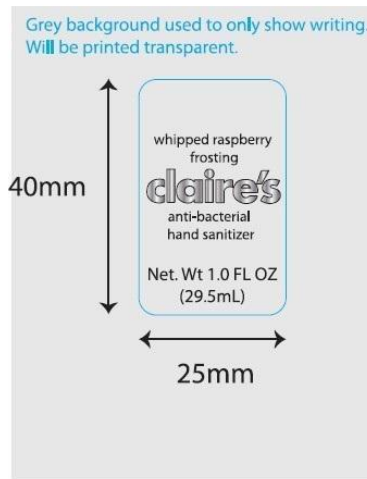
Other Information:

Store below 110 F.

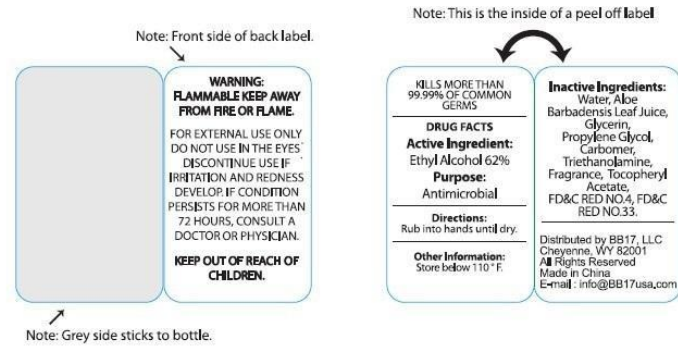
Inactive Ingredients:

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

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:53603-1017
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53603-1017-1	29.5 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	12/26/2014	

Labeler - BB17, LLC (828378294)

Revised: 12/2014

BB17, LLC