ANTI-BACTERIAL HAND GEL- ethyl alcohol gel
Jean Pierre Inc.

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 Antiseptic

Warnings: For external use only. Flammable. Keep away from fire or flame. Do not apply around eyes. Do not use in ears or mouth. When using this product, avoid contact with eyes. In case of contact, flush eyes with water.

Stop use or ask for a doctor if redness or irritation develops and persists for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

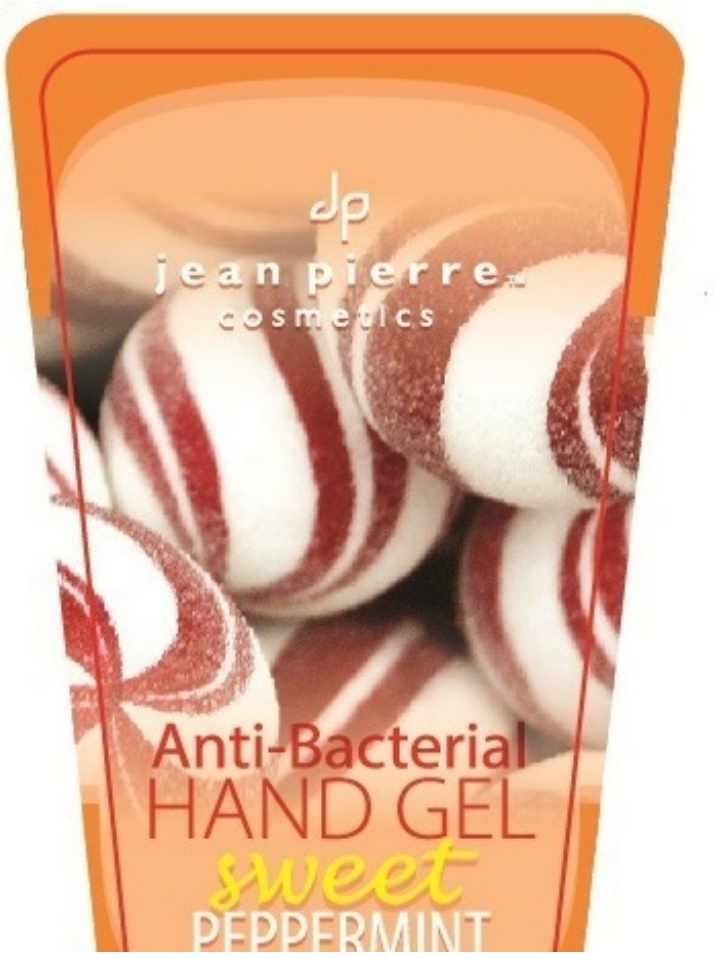
Directions: Squeeze as needed into your palms and thoroughly spread on bottom hands. Rub into skin until dry.

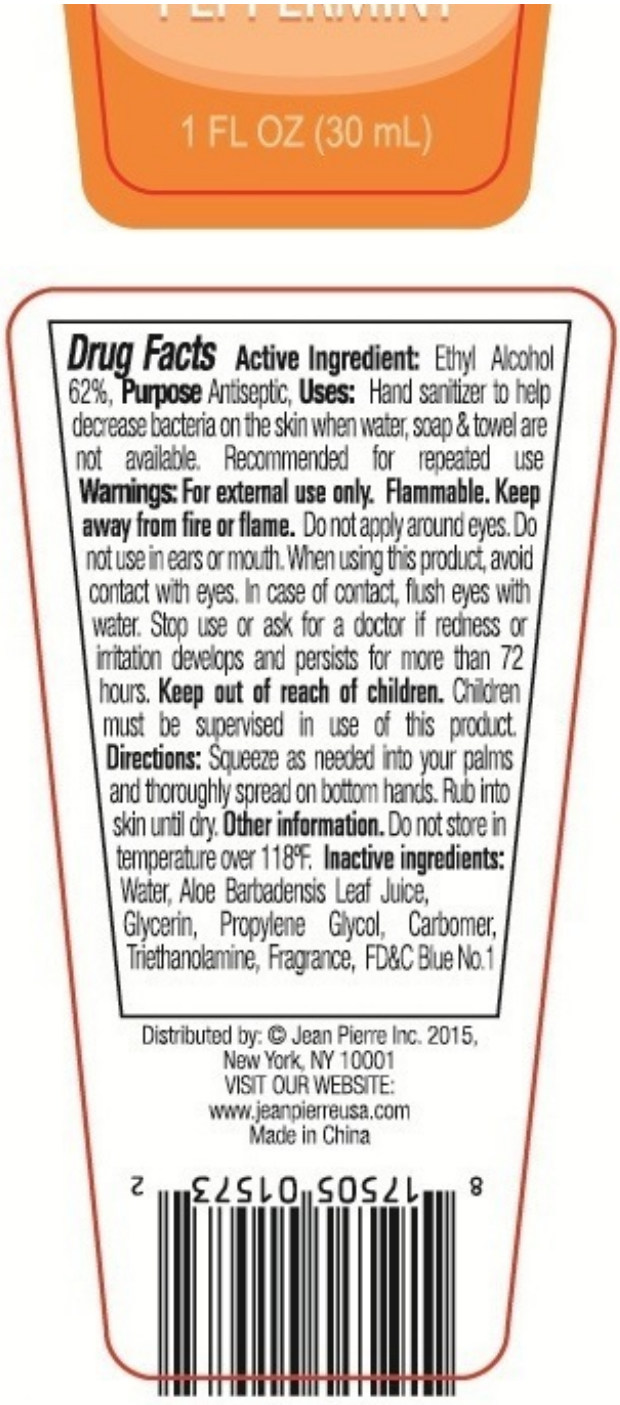
Inactive ingredients: Water, Aloe Barbadenis Leaf, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, FD&C Blue No.1

Uses: Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available. Recommended for repeated use

Other information

Do not store in temperature over 118 F.





ANTI-BACTERIAL HAND GEL

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70483-001
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70483-001-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/25/2016	

Labeler - Jean Pierre Inc. (138328393)

Revised: 5/2016 Jean Pierre Inc.