

ANTIMICROBIAL HAND SANITIZER GEL- alcohol gel gel
Hanover Pen Corp dba HPC Global

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.

Antimicrobial Hand Sanitizer

alcohol gel

Active Indgredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on skin.
- Recommended for repeated use.

Warnings

for external use only.

Flammable, keep away from fire or flame.

Do not use in the eyes, if this happens rinse thoroughly with water.

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

Keep out of reach of children.

If ingested get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product allow to dry without wiping
- children under six should be supervised while using this product.

Inactive Ingredients

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

Antimicrobial Hand Sanitizer Gel - Fresh 1.0 fl. oz.

Pkgd by HPC Global, Hanover PA, 17331 Made in USA

Lot# *****

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:518 11-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	20.699 mL in 29.57 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:518 11-721-10	29.57 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/13/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/13/2010	

Labeler - Hanover Pen Corp dba HPC Global (003022670)

Registrant - Robert Houghland (003022670)

Establishment

Name	Address	ID/FEI	Business Operations
Hanover Pen Corp dba HPC Global		003022670	relabel(518 11-721) , repack(518 11-721)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(518 11-721)

Revised: 1/2020

Hanover Pen Corp dba HPC Global