

HAND SANITIZER - alcohol 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.

Drug Facts

Active Ingredient

Ethyl Alcohol 66.5 percent

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

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

Stop use and ask a doctor

Stop use and ask a doctor if irritation or redness develops 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 and C number 5, D and C yellow number 10, fragrance, purified water, triethanolamine

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Front Label

NDC 51811-377-18

Hand Sanitizer - Fresh

8 FL OZ (237ML)

Back Label (Drug Facts)

Hand Sanitizer - Fresh

8 FL OZ (237ML)

Distributed by

HPC Global, Hanover PA 17331

Made in USA

Drug Facts

Active Ingredient	Purpose
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Uses

- For handwashing to decrease bacteria on skin without soap and water.
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Directions

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8 FL OZ (237ML)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:518 11-377
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	.665 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Trolamine (UNII: 9O3K93S3TK)	
Aloe (UNII: V5VD430YW9)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:518 11-377-18	237 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/01/2012	

Labeler - Hanover Pen Corp dba HPC Global (003022670)

Registrant - Hanover Pen Corp dba HPC Global (003022670)

Establishment

Name	Address	ID/FEI	Business Operations
Hanover Pen Corp dba HPC Global		003022670	repack, label

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture