

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%

Purpose

Antiseptic

Uses

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

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 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 produce.

Inactive Ingredients

aloe vera, carbomer, fragrance, purified water, triethanolamine

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Front Label

NDC 51811-375-28

Hand Sanitizer - Citrus

8 FL oz (237ML)

Back Label (Drug Facts)

Hand Sanitizer - Citrus

8 FL oz (237ML)

Distributed by

HPC Global, Hanover PA, 17331

Made in USA

The front label is a white, rounded rectangular shape with a black border. It contains the following text:

Drug Facts

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Hand Sanitizer - Citrus
8 FL OZ (237ML)

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

The back label is a light pink, rounded rectangular shape with a black border. It contains the following text:

NDC 51811-375-28

Hand Sanitizer - Citrus
8 FL OZ (237ML)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:518 11-375
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	0.665 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Trolamine (UNII: 9O3K93S3TK)	
Aloe (UNII: V5VD430 YW9)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:518 11-375-28	237 mL in 1 BOTTLE, PLASTIC		

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
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Safetec of America, Inc.

874965262

manufacture

Revised: 4/2012

Hanover Pen Corp dba HPC Global