

PURE GEL - alcohol gel
Phoenix Research Industries, 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.

Pure Gel 6605 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin, only when water is not available

Drug Facts Box OTC-Warnings Section

FLAMMABLE, keep away from fire and flames

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

wet hands thoroughly with product and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, triethanolamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis

Pure Gel 6605 18oz

660518P10010.jpg Pure Gel 18oz



Phoenix
RESEARCH INDUSTRIES, INC.
Simpler Sanitary Solutions

Pure Gel

Instant Hand Sanitizer

Contains Vitamin E and Aloe Vera!

Kills 99.99% of E. coli, Salmonella enterica and Staphylococcus aureus (MRSA) in 15 seconds.

DANGER: FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY.
See other cautions on opposite panel of label.
NET CONTENTS: 18 FL. OZ. (532 ml)



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Sold By:
PHOENIX RESEARCH INDUSTRIES, INC.
2865 North Berkeley Lake Rd.
Suite 6/7 • Duluth, Georgia 30096
Phone: (770) 455-7310 • Fax: (770) 455-1177

| Drug Facts | |
|---|----------------|
| Active Ingredient | Purpose |
| Ethyl Alcohol 62% | Antiseptic |
| Use for hand-washing to decrease bacteria on the skin, only when water is not available | |
| Warnings | |
| Flammable, keep away from fire and flames | |
| For external use only | |
| When using this product | |
| <ul style="list-style-type: none"> ■ do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water | |
| Stop use and ask a doctor if | |
| <ul style="list-style-type: none"> ■ irritation and redness develop | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away | |
| Directions | |
| <ul style="list-style-type: none"> ■ wet hands thoroughly with product and allow to dry without wiping | |
| Inactive Ingredients water, triethanolamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis | |

Batch No.:

660518P10010.1001

PURE GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50 452-221 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0K00R) | |
| CARBOMER 934 (UNII: Z135WT9208) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|-----------------------------|----------------------|--------------------|
| 1 | NDC:50 452-221-06 | 1 in 1 BOX | | |
| 1 | | 800 mL in 1 BAG | | |
| 2 | NDC:50 452-221-17 | 532 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:50 452-221-24 | 118 mL in 1 BOTTLE, PLASTIC | | |
| 4 | NDC:50 452-221-01 | 1200 mL in 1 CARTRIDGE | | |
| 5 | NDC:50 452-221-03 | 350 mL in 1 CARTRIDGE | | |
| 6 | NDC:50 452-221-05 | 540 mL in 1 BOTTLE, PLASTIC | | |
| 7 | NDC:50 452-221-07 | 700 mL in 1 BAG | | |
| 8 | NDC:50 452-221-09 | 2000 mL in 1 CARTRIDGE | | |
| 9 | NDC:50 452-221-10 | 1000 mL in 1 CARTRIDGE | | |

| | | | | |
|----|------------------|------------------------------|--|--|
| 10 | NDC:50452-221-11 | 1000 mL in 1 BOTTLE, PLASTIC | | |
| 11 | NDC:50452-221-12 | 1000 mL in 1 BAG | | |
| 12 | NDC:50452-221-13 | 800 mL in 1 BAG | | |
| 13 | NDC:50452-221-14 | 3785 mL in 1 BOTTLE, PLASTIC | | |
| 14 | NDC:50452-221-15 | 946 mL in 1 BOTTLE, PLASTIC | | |
| 15 | NDC:50452-221-28 | 149 mL in 1 BOTTLE, PLASTIC | | |
| 16 | NDC:50452-221-27 | 800 mL in 1 CARTRIDGE | | |
| 17 | NDC:50452-221-55 | 208200 mL in 1 DRUM | | |
| 18 | NDC:50452-221-08 | 1 in 1 BOX | | |
| 18 | | 1000 mL in 1 BAG | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333 | 02/01/2010 | |

Labeler - Phoenix Research Industries, Inc. (152259904)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| ABC Compounding Co., Inc. | | 003284353 | manufacture |

Revised: 3/2010

Phoenix Research Industries, Inc.