GERM SAFE - alcohol liquid Original 7, 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.

Germ Safe 6585 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62% v/v

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

press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand

rub hands together and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredient Section

water, DEA-C8-18 perfluoroalkylethyl phosphate, propylene glycol, fragrance

Germ Safe 6585 50ml

6585Z1P10145.jpg



Instant Foaming Hand Sanitizer

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: 50 ml (1.7 oz)

Sold By:

Original **7**®

849 Pickens Industrial Drive • Suite 1 Marietta, GA 30062 • Phone: 770-794-8511 Toll Free: 800-736-8465

> Please visit us at our website: www.original7.net

Drug Facts

Active Ingredient Ethyl Alcohol 62% v/v.....Antiseptic

Purpose

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

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

■ irritation and redness develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions ■ press pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand ■ rub hands together and allow to dry without wiping

Inactive Ingredients water, DEA-C8-18 perfluoroalkylethyl phosphate, propylene glycol, fragrance

Batch No: 6585Z1P10145 1306

GERM SAFE

alcohol liquid

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:14209-855 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Maiety

| Active ingredient/Active infoiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.62 mL in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength | | |
|--|----------|--|--|
| WATER (UNII: 059QF0KO0R) | | | |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3) | | | |
| DIETHANOLAMINE BIS(C8-C18 PERFLUOROALKYLETHYL)PHOSPHATE (UNII: 4J55VM509S) | | | |

Dackaging

| rackaging | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:14209-855-06 | 1 in 1 BOX | | |
| 1 | | 800 mL in 1 BAG | | |

| 2 | NDC:14209-855-17 | 532 mL in 1 BOTTLE, PLASTIC |
|----|------------------|------------------------------|
| 3 | NDC:14209-855-24 | 118 mL in 1 BOTTLE, PLASTIC |
| 4 | NDC:14209-855-01 | 1200 mL in 1 CARTRIDGE |
| 5 | NDC:14209-855-03 | 350 mL in 1 CARTRIDGE |
| 6 | NDC:14209-855-05 | 540 mL in 1 BOTTLE, PLASTIC |
| 7 | NDC:14209-855-07 | 700 mL in 1 BAG |
| 8 | NDC:14209-855-09 | 2000 mL in 1 CARTRIDGE |
| 9 | NDC:14209-855-10 | 1000 mL in 1 CARTRIDGE |
| 10 | NDC:14209-855-11 | 1000 mL in 1 BOTTLE, PLASTIC |
| 11 | NDC:14209-855-12 | 1000 mL in 1 BAG |
| 12 | NDC:14209-855-13 | 800 mL in 1 BAG |
| 13 | NDC:14209-855-14 | 3785 mL in 1 BOTTLE, PLASTIC |
| 14 | NDC:14209-855-15 | 946 mL in 1 BOTTLE, PLASTIC |
| 15 | NDC:14209-855-28 | 149 mL in 1 BOTTLE, PLASTIC |
| 16 | NDC:14209-855-27 | 800 mL in 1 CARTRIDGE |
| 17 | NDC:14209-855-55 | 208200 mL in 1 DRUM |
| 18 | NDC:14209-855-08 | 1 in 1 BOX |
| 18 | | 1000 mL in 1 BAG |
| 19 | NDC:14209-855-16 | 236 mL in 1 BOTTLE, PLASTIC |
| 20 | NDC:14209-855-18 | 50 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 | 09/01/2009 | |
| | | | |

Labeler - Original 7, Inc. (926622101)

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

| Establishment | | | | |
|---------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| ABC Compounding Co., Inc. | | 003284353 | manufacture(14209-855) | |

Revised: 6/2013 Original 7, Inc.