

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%

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 Germ Safe 50ml



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	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

- 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 perfluoro-alkylethyl phosphate, propylene glycol, fragrance

6585Z1P10145_0908

Batch No:

GERM SAFE

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14209-585
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14209-585-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:14209-585-17	532 mL in 1 BOTTLE, PLASTIC		

3	NDC:14209-585-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:14209-585-01	1200 mL in 1 CARTRIDGE		
5	NDC:14209-585-03	350 mL in 1 CARTRIDGE		
6	NDC:14209-585-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:14209-585-07	700 mL in 1 BAG		
8	NDC:14209-585-09	2000 mL in 1 CARTRIDGE		
9	NDC:14209-585-10	1000 mL in 1 CARTRIDGE		
10	NDC:14209-585-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:14209-585-12	1000 mL in 1 BAG		
12	NDC:14209-585-13	800 mL in 1 BAG		
13	NDC:14209-585-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:14209-585-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:14209-585-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:14209-585-27	800 mL in 1 CARTRIDGE		
17	NDC:14209-585-55	208200 mL in 1 DRUM		
18	NDC:14209-585-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:14209-585-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:14209-585-18	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	part333	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

Revised: 3/2010

Original 7, Inc.