

HAND SANITIZER- ethyl alcohol gel

Orazen 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.

Active Ingredient:

Ethyl Alcohol 62% w/w

Purpose

Antiseptic

Warnings

Flammable, keep away from fire or flame.

For external use only.

Stop use and ask a doctor if irritation and redness develops and persists for more that 72 hours.

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

Directions

- Wet hands thoroughly with product
- Briskly rub hands together until dry
- Supervise children in the use of this product

Inactive Ingredients

water, carbomer, fragrance, triethanoamine, glycerin, propylene glycol, isopropyl alcohol, isopropyl myristate, tocopheryl acetate, aloe vera extract

Other Information

- Store at room temperature 15 to 30C (59 to 86F)
- May discolor certain fabrics

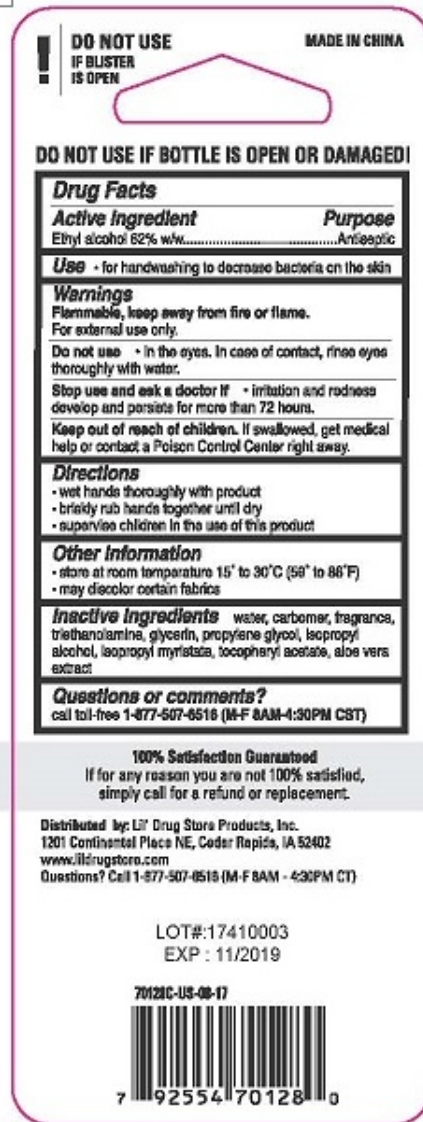
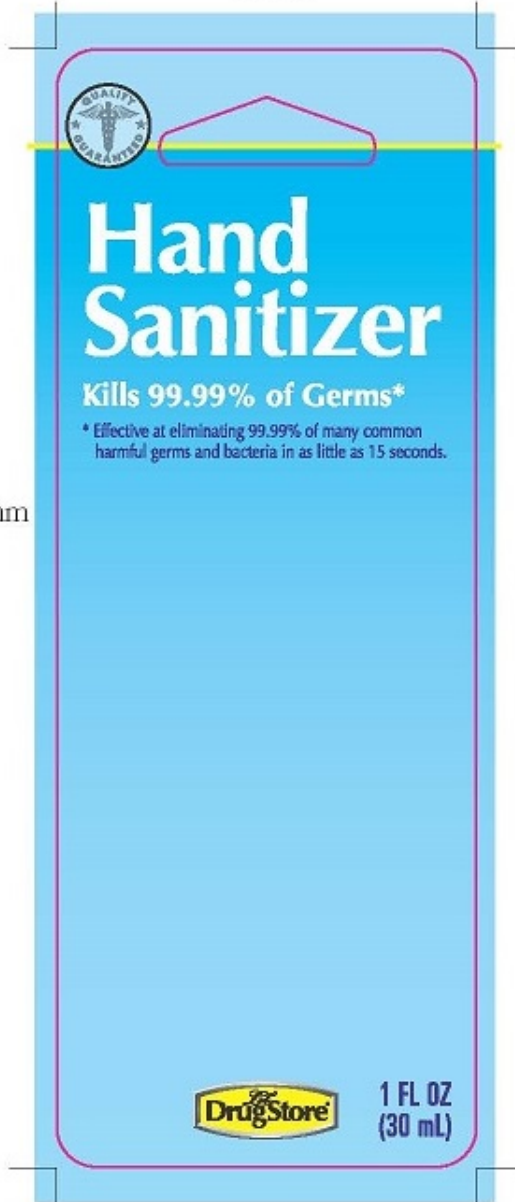
Use

For hand washing to decrease bacteria on the skin

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

57mm

152mm



Hand Sanitizer

Kills 99.99% of Most Common Germs that may Cause Illness

Distributed by:

Lil' Drug Store Products, Inc.
Cedar Rapids, IA 52402
Made in China



1 FL OZ (30 mL)

**Bottle Front
Clear Label**

Drug Facts *Active ingredient* Ethyl alcohol 62% w/w *Purpose* Antiseptic
Use • for handwashing to decrease bacteria on the skin *Warnings* **Flammable, keep away from fire or flame.** For external use only. **Do not use** • in the eyes. In case of contact, rinse eyes thoroughly with water. **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 swallowed, get medical help or contact a Poison Control Center right away. *Directions* • wet hands thoroughly with product • briskly rub hands together until dry • supervise children in the use of this product *Other information* • store at room temperature 15° to 30°C (59° to 86°F) • may discolor certain fabrics *Inactive ingredients* water, carbomer, fragrance, triethanolamine, glycerin, propylene glycol, isopropyl alcohol, isopropyl myristate, tocopheryl acetate, aloe vera extract
Questions or comments? call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)

**Bottle Back
Opaque Label**

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-001-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/11/2017	

Labeler - Orazen Inc (080916640)

Revised: 12/2017

Orazen Inc