# HAND SANITIZER- hand sanitizer gel Fortress Expert Co., Ltd

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.

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#### FrtrssTricstlIvryOrngYllwlHndSntzrAlch62

#### Active ingredient

Alcohol 62%

#### **Purpose**

Antiseptic

#### Use

■ For handwashing to decrease bacteria on the skin ■ Recommended for repeated use

#### **Warnings**

- For external use only
- **Flammable**, keep away from open flame and sources of heat
- Does not contain grain alcohol; do not drink. If taken internally will produce gastric distrubances.

#### When using this product

- Avoid the eyes and mucoous membranes
- In the case of eyes or mucous membranes contacr, rinse area thoroughly with water

#### Stop use and ask a doctor if

- Condition worsens
- Redness or irritation develops
- Condition persists for more than 3 days

#### Keep out of reach of children

■ If swallowed, contact a doctor or Poison Control Center immediately

#### Directions

- Rub dime sized amount between hands until dry.
- Supervise children in the use of this product.
- In the case of eye contact, rinse eyes thoroughly with water.

#### Other information

- Store below 105°F
- May discolor some fabrics.

### **Inactive ingredients**

Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Fragrance, PEG-40 Hydrogenated Castor Oil, FD&C YELLOW NO.5, D&C RED NO.33

#### Questions?

**■** 1-800-278-9218

#### **Package Label**





**Package Label** 



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This product has been granted the Good Housekeeping Seal.

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#### Drug Facts

Active Ingredient Alcohol 62%

Use ■ For handwashing to decrease bacteria on the skin ■ Recommended for repeated use

Purpose

Antiseptic

#### Drug Facts (continued)

#### Warnings

- For external use only
   Flammable, keep away from fire and flame
- Does not contain grain alcohol; do not drink. If taken internally will produce serious gastric

#### When using this product

Avoid the eyes and mucous membranes

#### Drug Facts

(continued)

■ In the case of eyes or mucous membranes contact, rinse area thoroughly with water

Stop use and ask a

- doctor if
  Condition worsens
  Redness or irritation develops
  Condition persists for more than 3 days

Keep out of reach of children

#### Drug Facts

disturbances.

(continued)

■If swallowed contact a doctor or Poison Control Center immediately.

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   Supervise children in the use of this product.
   In the case of eye contact, rinse eyes thoroughly with water.

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#### Drug Facts

(continued)

■ May discolor some fabrics.

#### Inactive ingredients Water, Acrylates/C10-30 Alkyl

Acrylate Crosspolymer, Triethanolamine, Fragrance,PEG-40 Hydrogenated Castor Oil, FD&C YELLOW NO.5,D&C RED

#### **Questions?**

■1-800-278-9218

#### **Package Label**







### HAND SANITIZER

hand sanitizer gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73549-011		
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	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 9O3K93S3TK)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

Packaging					
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1 NDC:73549-011-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			
Marketing Inf	ormation				
Marketing Inf		Marketing Start Date	Marketing End Date		
Marketing Inf Marketing Catego OTC monograph not fi	ry Application Number or Monograph Citation	Marketing Start Date 07/30/2020	Marketing End Date		

## **Labeler -** Fortress Expert Co., Ltd (543358697)

Establishment						
Name	Address	ID/FEI	Business Operations			
Fortress Expert Co., Ltd		543358697	manufacture (73549-011)			

Revised: 8/2020 Fortress Expert Co., Ltd