

## **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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### **008 HAND SANITIZER**

#### **Active ingredient**

Ethyl alcohol 62%

#### **Purpose**

Antiseptic

#### **Uses**

Helps reduce bacteria that potentially can cause disease

Helps prevent cross contamination on contact

Recommended for repeated use

#### **Warnings**

Flammable, keep away from open flame and sources of heat

External use only

Avoid contact with eyes , in the case of eyes contact, rinse eyes thoroughly with water.

Stop use and consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if irritation develops

Keep out of reach of children

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#### **Keep out of reach of children**

Keep out of reach of children

If swallowed, call a poison control center or get medical help right away .

#### **Directions**

Wet hands thoroughly with product and rub completely covering hands

·Allow to dry without wiping

·Children under the age of 6 should use with adult supervision

Not recommended for infants

## Other information

Store below 105F(41C)

May discolor certain fabrics or surfaces.

## Inactive ingredients

Water, Acrylates/C10- Alkyl Acrylate Crosspolymer, Triethanolamine, Fragrance

PEG-40 Hydrogenated Castor Oil. May man FD&C RED NO 4( 14700), D& REN0.33(C 17200), FD&C YELLOW NO 5(C 19140), FD&C BLUE NO. 1(CI 42090)

## Package Label Principal Display Panel

### FRONT LABEL

SUBSTRATE: WHITE SUBSTRATE,  
GLOSSY LAMINATION  
PRINTING: 4C PROCESS

25x41mm



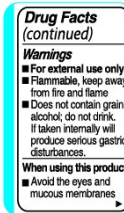
薰衣草款

### FOLD OUT BACK LABEL - ENGLISH

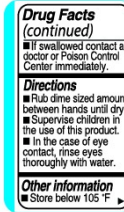
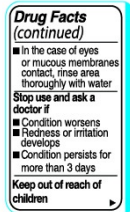
SUBSTRATE/FINISH: ART PAPER, GLOSSY LAMINATION  
PRINTING: 1C SPOT - BLACK INK

\*FTY, PLEASE USE PURPLE INGREDIENT & RESIZE LABEL TO FIT

第一页



第二页



第三页



**FRONT LABEL**

**SUBSTRATE/FINISH:**  
ART PAPER, MATTE LAMINATION  
**PRINTING: 4C PROCESS**

33x58mm

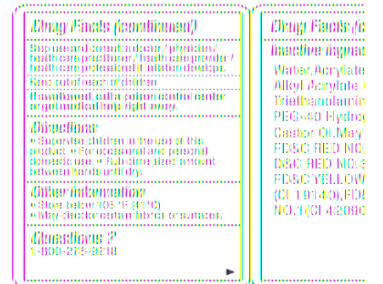
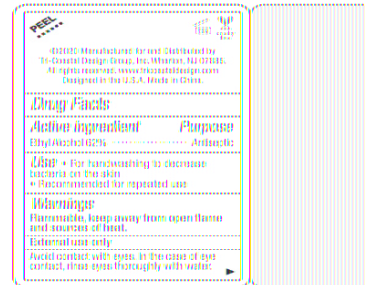


正贴4色过哑胶

**ANTI-BAC BACK LABEL**

**SUBSTRATE/FINISH:** ART PAF  
**PRINTING: 4C PROCESS**

33x52.6mm



复合贴文

**FRONT LABEL**

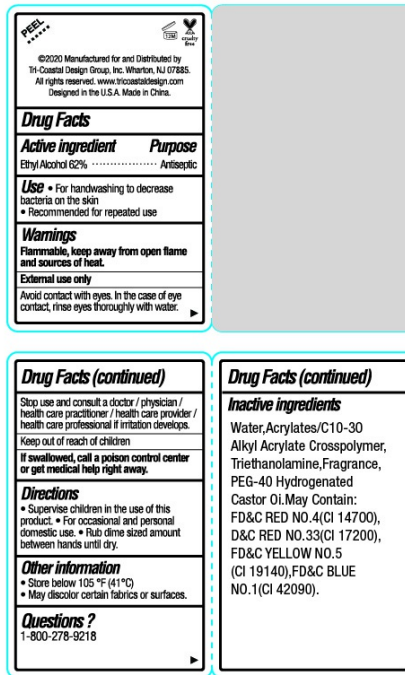
**SUBSTRATE/FINISH:**  
ART PAPER, MATTE LAMINATION  
**PRINTING:** 4C PROCESS



正贴4色过哑胶

**ANTI-BAC BACK LABEL**

**SUBSTRATE/FINISH:** ART PAPER, GLOSSY  
**PRINTING:** 4C PROCESS



复合贴 过光胶

**FRONT LABEL**

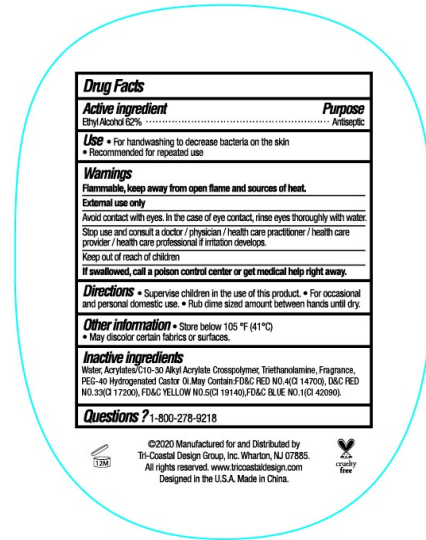
SUBSTRATE/FINISH: ART PAPER, MATTE LAMINATION  
 PRINTING: 4C PROCESS



正贴4色过哑胶

**ANTI-BAC BACK LABEL**

SUBSTRATE/FINISH: ART PAPER, GLOSSY  
 PRINTING: 4C PROCESS



反贴 过光胶

**HAND SANITIZER**

hand sanitizer gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73549-008
<b>Route of Administration</b>	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)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
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	Marketing Start Date	Marketing End Date
1	NDC:73549-008-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2020	
2	NDC:73549-008-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2020	
3	NDC:73549-008-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2020	
4	NDC:73549-008-04	1800 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/23/2020	

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

**Registrant** - Fortress Expert Co., Ltd (543358697)

### Establishment

Name	Address	ID/FEI	Business Operations
Fortress Expert Co., Ltd		543358697	manufacture(73549-008)

Revised: 7/2020

Fortress Expert Co., Ltd