

**FOCAN LLC AFFEX CARE HAND SANITIZER(AC01-04-01)- alcohol gel  
SHANTOU S.E.Z BAOJIE INDUSTRY 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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**Focan LLC Affex Care Hand Sanitizer**

**active ingredients**

Alcohol :62% v/v. Purpose: Antiseptic

**Antiseptic**

hand sanitizer

**use**

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

**Warnings**

For external use only. Flammable. Keep away from heat or flame

**Do not use**

In children less than 2 months of age. On open skin wounds

When using this product keep out of eyes ears and mouth. In case of contact with eyes rinse eyes throughly with water

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

keep out of reach of children. If swallowed get medical help or contact a poison control center right away

**Direction**

Place enough product on hands to cover all surfaces.Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C(104F)

**Inactive ingredients**

Water, Peg-40 Castor oil, Carbomer ,sodium hydroxide ,Tocopherol



# AFFEX<sup>®</sup> HAND HYGIENE

AC01-04-1



75% ETHYL ALCOHOL  
HAND SANITIZER  
Disinfectante con alcohol para manos

### Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 75% v/v.....	Antiseptic

**Uses** ■ hand sanitizer to help decrease bacteria on the skin, when water, soap & towel are not available. ■ recommended for repeated use.

### Warnings

For external use only. Flammable. Keep away from fire or flame.

Do not apply around eyes. Do not use in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

**Directions** ■ pump as needed into your palms and thoroughly spread on both hands. ■ rub into skin until dry.

**Other information** ■ store at 20°C (68°F to 77°F). ■ may discolor fabrics.

**Inactive ingredients** Water, PEG-40 Hydrogenated Castor Oil, Carbomer, Sodium Hydroxide, Tocopherol.

## 4L (4000mL)

DISPOSE OF CONTENTS and CONTAINER in Accordance with LOCAL, REGIONAL, NATIONAL, or INTERNATIONAL REGULATIONS.

STORE IN A WELL-VENTILATED PLACE. KEEP COOL.

\*\* CONTAINS ETHYL ALCOHOL \*\*  
NON-STERILE SOLUTION

KEEP OUT OF REACH OF CHILDREN  
MANTÉNGASE ALEJADO DEL ALCANCE DE LOS NIÑOS



Made in PRC

Questions? Call (888) 395-2206  
Between 8:00AM-5:00PM  
Monday-Friday (CST)

Distributed by: AFFEX<sup>®</sup> 1400 AFFLINK Place, Tuscaloosa, AL 35406 (888) 395-2206

**FOCAN LLC AFFEX CARE HAND SANITIZER(AC01-04-01)**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:749 13-555
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	23.2 mL in 100 mL
TOCOPHEROL (UNII: R0ZB2556P8)	0.5 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.3 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:749 13-555-02	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2020	

**Labeler** - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)**Registrant** - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)**Establishment**

Name	Address	ID/FEI	Business Operations
SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD		546345856	manufacture(749 13-555)

Revised: 6/2020

SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD