

FOCAN LLC PERFORMANCE PLUS HAND SANITIZER GEL- 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.

FOCAN LLC PERFORMANCE PLUS HAND SANITIZER GEL

Active Ingredient(s)

Alcohol :62% v/v. Purpose: Antiseptic

Purpose

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 thoroughly 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.

Directions

- 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 940, SODIUM HYDROXIDE, TOCOPHEROL

Package Label - Principal Display Panel



PP-28175



ETHYL ALCOHOL-BASED ANTISEPTIC, 75%
HAND SANITIZER GEL
Desinfectante De Gel con alcohol etílico para manos

NON-STERILE SOLUTION

4 L (1.06 US gal)

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.



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 **



RECOMMENDED FOR INDUSTRIAL USE
KEEP OUT OF REACH OF CHILDREN
PARA USO INDUSTRIAL SOLAMENTE
MANTÉNGASE ALEJADO DEL ALCANCE DE LOS NIÑOS



Made in PRC



Distributed By: RJ Schinner Co. Inc. N89W14700 Patrita Drive, Menomonee Falls, WI 53051 (800) 234-1460

FOCAN LLC PERFORMANCE PLUS HAND SANITIZER GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74913-444 |
| Route of Administration | 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 |
|--------------------------------------|-------------------|
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | 0.3 mL in 100 mL |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) | 0.5 mL in 100 mL |
| TOCOPHEROL (UNII: R0ZB2556P8) | 0.5 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 23.2 mL in 100 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.5 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74913-444-01 | 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(74913-444) |