

PROTOCOL-80 HAND SANITIZER- alcohol gel
Jiangsu Jinze Biotechnology 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.

Protocol-80 Hand Sanitizer Gel

This is a hand sanitizer formulated to contain an 80% Alcohol Content

Active Ingredient(s)

Alcohol 80% 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.

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

glycerin, hydrogen peroxide, purified water USP, Aloe extract, Carbomer, Triethanolamine

Package Label - Principal Display Panel

500 mL NDC: 74717-800-01

| Drug Facts | |
|---|------------|
| Active ingredient[s] | Purpose |
| Alcohol 80% v/v..... | Antiseptic |
| Use[s] | |
| 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 | |
| <ul style="list-style-type: none"> 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 | |
| <ul style="list-style-type: none"> 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 | |
| <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients | |
| glycerin, purified water USP, Glycerin, Aloe extract, Carbomer, Triethanolamine | |

3.8 mL NDC: 74717-800-2

| Drug Facts | |
|---|------------|
| Active ingredient[s] | Purpose |
| Alcohol 80% v/v..... | Antiseptic |
| Use[s] | |
| 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 | |
| <ul style="list-style-type: none"> 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 | |
| <ul style="list-style-type: none"> 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 | |
| <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients | |
| glycerin, purified water USP, Glycerin, Aloe extract, Carbomer, Triethanolamine | |

PROTOCOL-80 HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74717-800 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 80 mL in 100 mL | |
|--|--|---|----------------------|--------------------|
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| TROLAMINE (UNII: 9O3K93S3TK) | | | 0.3 mL in 100 mL | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | | | 0.35 mL in 100 mL | |
| ALOE (UNII: V5VD430YW9) | | | 0.5 mL in 100 mL | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 5 mL in 100 mL | |
| WATER (UNII: 059QF0K00R) | | | 13.35 mL in 100 mL | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:74717-800-01 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/23/2020 | |
| 2 | NDC:74717-800-02 | 3.8 mL in 1 POUCH; Type 0: Not a Combination Product | 04/24/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 04/23/2020 | | |

Labeler - Jiangsu Jinze Biotechnology Co., Ltd. (554220866)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Jiangsu Jinze Biotechnology Co., Ltd. | | 554220866 | manufacture(74717-800) |

Revised: 4/2020

Jiangsu Jinze Biotechnology Co., Ltd.