# PFA STRONGHOLD SANITIZING HANDLOTION ROSE- alcohol lotion STRONGHOLD TRADING LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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## 80969-008-01 PFA STRONGHOLD SANITIZING HAND LOTION\_ROSE

## **Active ingredient**

Alcohol 62%

#### **Purpose**

Sanitizer

#### Use

Hand sanitizing to help reduce bacteria on the skin.

#### Warnings

For external use only.

Flammable. Keep away from fire or flame.

# When using this product

avoid contact with the eyes.

In case of contact, flush eyes thoroughly with water.

# Stop use and ask a doctor

if irritation and redness develops and persists.

## Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- Put enough product in the palm to cover hands & rub together briskly the liquid is dry
- Children under 6 should be supervised when using Sanitizers.

#### Other information

- Store below 77°F (25°C)
- May discolor certain fabrics or surfaces.

## **Inactive ingredients**

Water, Butyrospermum Parkii (Shea) Butter, Cetearyl Alcohol, PEG-60 Hydrogenated Castor Oil, Glyceryl Stearate, Glycerin, PEG-100 Stearate, Ammonium Polyacryloyldimethyl Taurate, Caprylic/Capric Triglyceride, Rosa Damascena Flower Water, Centella Asiatica Extract, Polysorbate 80, Fragrance, Citronellol, Eugenol, Geraniol, Hexyl Cinnamal

#### Package Label

80<sub>mm</sub>

60<sub>mm</sub>





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# PFA STRONGHOLD SANITIZING HANDLOTION ROSE alcohol lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

| Active Ingredient/Active Moiety                        |                          |                 |  |
|--|--------------------------|-----------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength        |  |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL                  | 62 mL in 100 mL |  |

| Inactive Ingredients   |          |
|--|----------|
| Inactive Ingredients   |          |
| Ingredient Name  | Strength |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                          |          |
| WATER (UNII: 059QF0KO0R)   |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)                                 |          |
| POLYOXYL 60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)                 |          |
| .ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)                           |          |
| GERANIOL (UNII: L837108USY)  |          |
| EUGENOL (UNII: 3T8H1794QW)   |          |
| SHEA BUTTER (UNII: K49155WL9Y)   |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                                      |          |
| .BETACITRONELLOL, (R)- (UNII: P010UT964K)                              |          |
| ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)                           |          |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)                               |          |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| POLYOXYL 100 STEARATE (UNII: YD01N1999R)                               |          |
| AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371) |          |
| CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)                     |          |

| Packaging |                                 |  |                         |                       |
|-----------|---------------------------------|--|-------------------------|-----------------------|
| #         | # Item Code Package Description |  | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:80969-008-<br>01            | 2 mL in 1 POUCH; Type 0: Not a Combination Product | 01/26/2023              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| unapproved drug other |   | 01/26/2023              |                       |
|                       |   |                         |                       |

# Labeler - STRONGHOLD TRADING LLC (117694134)

# **Registrant -** S-ONE PHARMACEUTICAL INC (694626932)

| Establishment            |         |           |                        |  |
|--------------------------|---------|-----------|------------------------|--|
| Name                     | Address | ID/FEI    | Business Operations    |  |
| S-ONE PHARMACEUTICAL INC |         | 694626932 | manufacture(80969-008) |  |

Revised: 1/2023 STRONGHOLD TRADING LLC