

WOW HAND SANITIZER- alcohol gel
SUJANIL CHEMO INDUSTRIES

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.

WOW Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Wow Hand Sanitizer Gel 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.

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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

Package Label - Principal Display Panel

The image shows the front and back views of the WOW Hand Sanitiser package label. The front view (left) features the brand name 'WOW' in large, stylized white letters on a blue background, with 'INSTANT HAND SANITISER' below it. It highlights 'aloe vera' and 'neem' ingredients with green circular icons. A central claim states 'KILLS 99.9% GERMS WITHOUT WATER'. At the bottom, there is a circular logo for '50 YEARS OF HEALTH & HAPPINESS' by 'Sujanil's' and an image of hands being washed. The back view (right) contains detailed usage instructions, ingredients, and safety information. It lists ingredients: Ethanol 70%, Aqua, Glycerin, PG, Carbomer, IPA, TEA, Aloe vera extract, and Neem extract, Perfume. Usage instructions include: 'When to Use: Use it as often as required through the day, particularly before eating, after public transport, after hospital/meeting, after coughing/sneezing, and after playing with pets.' It also provides a three-step application guide: 1. Take coin size drop on your hand, 2. Rub hands together, 3. Cover all surface until hands feel dry (20 sec.). A cautionary note states: 'CAUTION: Keep away from fire or flame & children. Consult a Doctor if irritation occurs or product is swallowed.' The back view also includes the expiration date 'EXP. DATE: 2 YEARS FROM DATE OF MANUFACTURING', manufacturing details (Mfg. Lic.NO.: PD/C/72, Lot No., Mfg Date), net contents, and a barcode with the number 8906021590884. The manufacturer is 'sujanil chemo industries' (69, Wanawadi Industrial Area, Pune - 411040) and the importer is 'Highly Flammable Made in India'. The website 'www.sujanil.com' is listed at the bottom.

85 x 130 mm - front

85 x 130 mm - back

100 mL NDC:76441-904-91

WOW HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76441-900 |
| 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 |
|--------------------------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:76441-900-09 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/30/2020 | |
| 2 | NDC:76441-900-90 | 200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/30/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 06/30/2020 | |

Labeler - SUJANIL CHEMO INDUSTRIES (650280816)**Registrant** - SUJANIL CHEMO INDUSTRIES (650280816)

Revised: 6/2020

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