NON-WASH DISINFECTANT- alcohol liquid NON-WASH SANITISERGEL- alcohol liquid Shera Heman Zhejiang Biotechnologies 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.

Non-wash Disinfectant

Non-wash Disinfectant; Non-wash Sanitiser Gel

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Non-wash Disinfectant, Non-wash Sanitiser 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

Non-wash Disinfectant:

purified water USP

Non-wash Sanitiser Gel:

WATER CARBOMER GLYCERIN

Package Label - Principal Display Panel





NON-WASH DISINFECTANT

alcohol liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74457-101 |
| 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 |
| WATER (UNII: 059QF0KO0R) | |

| Pa | ckaging | | | |
|----|-----------|---------------------|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| 1 | NDC:74457-101-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
|----|----------------------|---|------------|--|
| 2 | NDC:74457-101- 02 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 3 | NDC:74457-101- 03 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 4 | NDC:74457-101- 04 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 5 | NDC:74457-101- 05 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 6 | NDC:74457-101- 06 | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 7 | NDC:74457-101- 07 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 8 | NDC:74457-101- 08 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 9 | NDC:74457-101- 09 | 4000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 10 | NDC:74457-101-10 | 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |
| 11 | NDC:74457-101-11 | 25000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 12/24/2020 | | |
| | | | | |

NON-WASH SANITISERGEL

alcohol liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74457-201 |
| 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 | | |
| WATER (UNII: 059QF0KO0R) | | | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |

| Pac | kaging | | | |
|-----|-----------|---------------------|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| 1 | NDC:74457-201-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
|----|----------------------|---|------------|
| 2 | NDC:74457-201- 02 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 3 | NDC:74457-201- 03 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 4 | NDC:74457-201- 04 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 5 | NDC:74457-201- 05 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 6 | NDC:74457-201- 06 | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 7 | NDC:74457-201- 07 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 8 | NDC:74457-201- 08 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 9 | NDC:74457-201- 09 | 4000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 10 | NDC:74457-201-10 | 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |
| 11 | NDC:74457-201-11 | 25000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/24/2020 |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 12/24/2020 | | |
| | | | | |

Labeler - Shera Heman Zhejiang Biotechnologies Co.,Ltd. (554528847)

| Establishment | | | |
|---|---------|-----------|------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Shera Heman Zhejiang Biotechnologies Co.,Ltd. | | 554528847 | manufacture (74457-101, 74457-201) |

Revised: 12/2020 Shera Heman Zhejiang Biotechnologies Co.,Ltd.