

## **SURFACE HAND SANITIZER- alcohol gel**

### **Welburn Corporation**

*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.*

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### **Surface Hand Sanitizer - Welburn Corporation**

#### **Drug Facts**

##### **Active ingredients**

Alcohol 70% v/v

##### **Purpose**

Antiseptic

##### **Uses**

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**

- On 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 thoroughly with water.

##### **Stop use and ask a doctor if**

- Stop use and seek 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, Carbomer, Glycerin, Aloe Barbadensis Leaf Juice, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

**Questions?**

call 888 387 3887

**Company Information**

Distributed by:

Welburn Corporation

Hermosa Beach, CA 90254

Made in Guatemala

**Product Packaging - 500ml**

WITH ALOE VERA

SURFACE

HAND SANITIZER

ANTISEPTIC GEL

MADE WITH 70% ALCOHOL

TRICLOSAN-FREE

FRAGRANCE-FREE

MOISTURIZING

16.9 FL OZ / 500ml

WITH  
ALOE  
VERA



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## SURFACE HAND SANITIZER

alcohol gel

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:77622-005 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 70 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX)                                 |          |
| CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)                    |          |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)              |          |
| TROLAMINE (UNII: 9O3K93S3TK)                                |          |
| WATER (UNII: 059QF0K00R)                                    |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                           |          |

### Packaging

| #                            | Item Code        | Package Description   | Marketing Start Date        | Marketing End Date        |
|------------------------------|------------------|---|-----------------------------|---------------------------|
| 1                            | NDC:77622-005-01 | 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   | 05/27/2020                  |                           |
| 2                            | NDC:77622-005-02 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2020                  |                           |
| 3                            | NDC:77622-005-04 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2020                  |                           |
| 4                            | NDC:77622-005-03 | 280 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2020                  |                           |
| 5                            | NDC:77622-005-05 | 458 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2020                  |                           |
| 6                            | NDC:77622-005-06 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/27/2020                  |                           |
| 7                            | NDC:77622-005-07 | 2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/27/2020                  |                           |
| 8                            | NDC:77622-005-08 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/27/2020                  |                           |
| 9                            | NDC:77622-005-09 | 1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product    | 05/27/2020                  |                           |
| 10                           | NDC:77622-005-10 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2020                  |                           |
|                              |                  |   |                             |                           |
| <b>Marketing Information</b> |                  |   |                             |                           |
| <b>Marketing Category</b>    |                  | <b>Application Number or Monograph Citation</b>                 | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| OTC monograph not final      |                  | part333A  | 05/27/2020                  |                           |

**Labeler** - Welburn Corporation (117515830)

Revised: 5/2020

Welburn Corporation