

## HAND SANITIZER- alcohol cloth Supplyaid Rapid Response

*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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Product is hand sanitizing wipes

- 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.
- Glycerol.
- Sosium Hyaluronate.
- Aloe extract
- Trolamine
- Water.
- Denatorium

### Active Ingredient(s)

| Drug Facts   |                              |
|--|------------------------------|
| <b>Active ingredient</b><br>Ethyl alcohol 80% v/v  | <b>Purpose</b><br>Antiseptic |
| <b>Use</b> Sanitizing wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. |                              |
| <b>Warnings</b> Flammable, keep away from heat or flame. For external use only. Not for use as a baby wipe.                            |                              |
| <b>Do not use</b> - on children less than 2 months of age - on damaged or sensitive skin   |                              |
| <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.      |                              |

|   |
|---|
| <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.   |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |
| <b>Directions</b> - Remove wipe from package. Reseal package to keep wipes from drying out. Then apply wipe to hands and clean thoroughly. - Supervise children under 6 years of age when using this product to avoid swallowing. |
| <b>Other information</b> - Store between 59-86°F (15-30°C) - Avoid freezing and excessive heat above 104°F (40°C)   |
| <b>Inactive ingredients</b> Glycerol, Aloe extract, Sodium Hyaluronate, Trolamine, Water (aqua), Denatonium   |

Alcohol 80% v/v. Purpose: Antiseptic

### Purpose

Antiseptic, Hand Sanitizer

## **Use**

Sanitizing wipes are used 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 damaged or sensitive skin

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**

- Remove wipe from package. Reseal package to keep wipes from drying out. Then apply wipe to hands and clean thoroughly.
- 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**

glycerol, aloe extract, sodium hyaluronate, trolamine, water, denatonium

## **Package Label - Principal Display Panel**



NDC: 74251-205-11

**HAND SANITIZER**

alcohol cloth

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:74251-205 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  |  | Basis of Strength                                   | Strength             |                    |
|--|--|---|----------------------|--------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) |  | ALCOHOL   | 80 mL in 100 mL      |                    |
| <b>Inactive Ingredients</b>                            |  |   |                      |                    |
| Ingredient Name  |  | Strength  |                      |                    |
| WATER (UNII: 059QF0KO0R)                               |  |   |                      |                    |
| ALOE (UNII: V5VD430YW9)                                |  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                            |  |   |                      |                    |
| DENATONIUM (UNII: 4IK22DF4OU)                          |  |   |                      |                    |
| TROLAMINE (UNII: 9O3K93S3TK)                           |  |   |                      |                    |
| <b>Packaging</b>                                       |  |   |                      |                    |
| #  | Item Code                                | Package Description                                 | Marketing Start Date | Marketing End Date |
| 1  | NDC:74251-205-11                         | 50 mL in 1 POUCH; Type 0: Not a Combination Product | 11/03/2020           |                    |
| <b>Marketing Information</b>                           |  |   |                      |                    |
| Marketing Category                                     | Application Number or Monograph Citation | Marketing Start Date                                | Marketing End Date   |                    |
| OTC monograph not final                                | part333A                                 | 09/03/2020  |                      |                    |

**Labeler** - Supplyaid Rapid Response (117468023)

**Registrant** - SUMEC Hardware & Tools Co. Ltd. (654687771)

### Establishment

| Name                         | Address | ID/FEI    | Business Operations    |
|------------------------------|---------|-----------|------------------------|
| Supplyaid Rapid Response LLC |         | 117468023 | manufacture(74251-205) |

Revised: 11/2021

Supplyaid Rapid Response