#### HAND SANITIZER- alcohol liquid Washington State University

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.

-----

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

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

- 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.

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.

#### 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

237 mL NDC: 74363-001-01

# Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



354 mL NDC: 74363-001-02

# Alcohol Antiseptic 80% Topical Solution

# Hand Sanitizer Non-Sterile Solution



| Active Ingredients                        |  | Purpose                        |  |
|---|--|--------------------------------|--|
| Alcohol 79%                               | Antisepti  |                                |  |
| Use(s):                                   |  | 0.000                          |  |
| Hand sanifizer to he<br>when soap and wab | lp reduce bacteria that potentially (<br>er are not available.           | can cause disease. Foruse      |  |
| Warnings:                                 |  |                                |  |
| Forexternaluae o                          | nly. Flammable . Keep away from  | nheatorflame                   |  |
| Do Not Use: In                            | children under 2 months of age   | On open skin wounds            |  |
| with eyes, rinse eye                      | od uct keep out of eyes, ears and<br>s thoroughly with water.            |                                |  |
| serious cond <b>i</b> ion                 | a doctorifinitation or rash occurs.                                      |                                |  |
| Control Centerright                       | of c hildrøn. If swallowed, get med<br>away.                             | lical help or contact a Poison |  |
| Directions                                | 985 65 6345 IN 95  | INCIDE AREA NO. ANDA           |  |
|   | ict on hands to cover all suifaces.<br>Inder б years of age when usingth |                                |  |
| s upervise children u<br>swallowing.      |  |                                |  |

| Drug Facta                               |   |                                      |  |  |
|--|---|--------------------------------------|--|--|
| Active Ingredients                       | ctive Ingredienta Purpos  |                                      |  |  |
| Alcohol 79%                              |   | Antiseptio                           |  |  |
| Use(s):                                  | ALL ALL PROPERTY AND A PARTY  | 201 0.0                              |  |  |
| Hand sanitizer to ho<br>when soap and wa | spreduce bacteriathat potentially (<br>er are not available.                | can cause disease. Foruse            |  |  |
| Warnings:                                |   |                                      |  |  |
| Forexternaluae o                         | nly. Flammable. Keep away from  | nheatorflame                         |  |  |
| Do Not Use:   Ir                         | children under 2 months of age  | On open skin wounds                  |  |  |
|  | roduct keep out of eyes, ears and<br>is thoroughly with water.              | mouth. In case of contact            |  |  |
| Stop use and ask<br>serious condition    | a doctorifinitation or rash occurs.   | These may be signs of a              |  |  |
| Keepout of reach                         | of children. If swallowed, get med  | lical help or contact a Poison       |  |  |
| Control Centerrigh                       | taway.  |                                      |  |  |
| Directions                               |   |                                      |  |  |
| Supervise children                       | uction hands to cover all surfaces. I<br>under 6 years of age when using th |                                      |  |  |
| swallowing.                              |   |                                      |  |  |
| Other Information                        | Store between 15-30C (59-<br>86F)   | Avoid freezing or<br>heat>40C (104F) |  |  |

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

# Alcohol Antiseptic 80% Topical Solution

## Hand Sanitizer Non-Sterile Solution



946 mL NDC: 74363-001-04

### Alcohol Antiseptic 80% Topical Solution

### Hand Sanitizer Non-Sterile Solution



100 mL NDC: 74363-001-05

### Alcohol Antiseptic 80% Topical Solution

## Hand Sanitizer Non-Sterile Solution



| Active Ingredients                        | C2   | Purpose                              |  |  |
|---|--|--------------------------------------|--|--|
| Alcohol 79%                               |  | Antiseptio                           |  |  |
| Use(s):                                   |  | 0.0000                               |  |  |
| Hand sanitizer to he<br>when soap and wat | ap reduce bacteria that potentially<br>er are not available.             | can cause disease. Foruse            |  |  |
| Warnings:                                 |  |                                      |  |  |
| Forexternaluae o                          | nly. Flammable. Keep away from   | nheatorflame                         |  |  |
| Do Not Use: In                            | children under 2 months of age   | On open skin wounds                  |  |  |
| with eyes, rinse eye                      | roduct keep out of eyes, ears and<br>2s thoroughly with water.           |                                      |  |  |
| Stopuse and ask:<br>serious condition     | a doctorifinitation or rash occurs                                       | . These may be signs of a            |  |  |
| Keepout of reach<br>Control Centerrigh    | of childrøn. If swallowed, get me<br>taway.                              | xical help or contact a Poison       |  |  |
| Directions                                | 103 103 103403 107 107 107 10  | PARTY PRACE AND TRAVES               |  |  |
|   | uct on hands to cover all surfaces.<br>under 6 years of age when using t |                                      |  |  |
| Other Information                         | Store between 15-30C (59-<br>86F)  | Avoid freezing or<br>heat>40C (104F) |  |  |

Inactive Ingredients: glycerin, hydrogen percoide, purified water

| Active Ingredier  | nta 🔤   | Purpose                        |  |  |
|---|---|--------------------------------|--|--|
| Alcohol 79%   |   | Antiseptio                     |  |  |
| Use(s):   | annen ta ta <sup>20</sup> annen enter anne                          | 65. 47                         |  |  |
|   | help reduce bacteria that potentially (<br>vater are not available. | an cause disease. Foruse       |  |  |
| Warnings:   |   |                                |  |  |
| Forexternaluae  | only. Flammable. Keep away from                                     | nheatorflame                   |  |  |
| Do Not Use:   | In children under 2 months of age                                   | On open skin wounds            |  |  |
| with eyes, rinse (                                      | i product keep out of eyes, ears and<br>eyes thoroughly with water. |                                |  |  |
| Stop use and as<br>serious condition                    | aka doctorifimitation orrash occurs.                                | These may be signs of a        |  |  |
|   | ch of children. If swallowed, get med                               | lical help or contact a Poison |  |  |
|   | ,,,   |                                |  |  |
| Keepout of rea<br>Control Centerni<br><i>Directions</i> | ,,,   |                                |  |  |
| Control Centerri<br>Directions<br>Place enough pr       | ,,,   |                                |  |  |

| Drug Facta                                   |  |                                      |  |  |
|--|--|--------------------------------------|--|--|
| Active Ingredients                           |  | Purpose                              |  |  |
| Alcohol 79%                                  |  | Antisepti                            |  |  |
| Use(s):                                      |  | 2020-2020 (A.M.)                     |  |  |
| Hand sanitizer to hell<br>when soap and wate | preduce bacteriathat potentially (<br>rrare not available.   | an cause disease. Foruse             |  |  |
| Warnings:                                    | LUNCTION OF STREET, ST | An 10280-400, Re-2003-0              |  |  |
| Forexternaluaeor                             | ily. Flammable. Keep away from   | nheatorflame                         |  |  |
| Do Not Use: In                               | children under 2 months of age   | On open skin wounds                  |  |  |
| with eyes, rinse eye:                        | od uct keep out of eyes, ears and<br>s thoroughly with water.  |                                      |  |  |
| Stop use and aska<br>serious condition       | doctor if initiation or rash occurs.   | These may be signs of a              |  |  |
| Keepout of reach o<br>Control Centerright    | of c hildrøn. If swallowed, get med<br>away.   | lical help or contact a Poison       |  |  |
| Directions                                   | THE TREAT PROPERTY OF  | organism source of which             |  |  |
|  | ct on hands to cover all surfaces. I   |                                      |  |  |
| Supervise children u<br>swallowing.          | nder 6 years of age when using th  | iis productto avoid                  |  |  |
| Other Information                            | Store between 15-30C (59-<br>86F)  | Avoid freezing or<br>heat>40C (104F) |  |  |
| Inactive Ingredient                          | a: glycerin, hydrogen peroxide, pu   | urified water                        |  |  |

Alcohol Antiseptic 80% Topical Solution

# Hand Sanitizer Non-Sterile Solution



| Drug Facta                                 |  |                                      |
|--|--|--------------------------------------|
| Active Ingredients                         |  | Purpose                              |
| Alcohol 79%                                |  | Antiseptic                           |
| Use(s):                                    |  |                                      |
| Hand sanitizer to he<br>when soap and wate | lp reduce bacteria that potentially<br>er are not available.   | can cause disease. Foruse            |
| Warninga:                                  | 60 X00 X X00 | 23 23 34                             |
| Forexternaluse or                          | ily. Flammable, Keep away from   | m heat or flame                      |
| Do Not Use: In                             | children under 2 months of age   | On open skin wounds                  |
| with eyes, rinse eye:                      | od uct keep out of eyes, ears and<br>s thoroughly with water.<br>doctor if infitation or rash occurs   |                                      |
| serious condition                          |  | . The child is chight of a           |
| Keepout of reach o<br>Control Centerright  | of children. If swallowed, get me<br>away.   | dical helpor contact a Poison        |
| Directions                                 | alla an exerce e   | 1000 000 000 000 00000               |
|  | ct on hands to cover all surfaces.<br>Inder 6 years of age when using t  |                                      |
| Other Information                          | Store between 15-30C (59-  | Avoid freezing or<br>heats40C (104E) |

86F) heat>40C (104F) Inactive Ingredients: glycerin, hydrogen peroxide, purified water

Dave Dave

750 mL NDC: 74363-001-07

# Alcohol Antiseptic 80% Topical Solution

### Hand Sanitizer Non-Sterile Solution



1000 mL NDC: 74363-001-08

| Active Ingredients                         | 0   | Purpose                              |  |  |
|--|---|--------------------------------------|--|--|
| Alcohol 79%                                |   | Antiseptio                           |  |  |
| Use(s):                                    |   | C.S. 4. (6. 7 a)                     |  |  |
| Hand sanitizer to he<br>when soap and wate | preduce bacteriathat potentially :<br>rrare not available.              | can cause disease. Foruse            |  |  |
| Warnings:                                  | Ge (64) 1441 552 574  | 318 #33554eV                         |  |  |
| Forexternal use or                         | ily. Flammable, Keep away from  | nheatorflame                         |  |  |
| Do Not Use:   In                           | children under 2 months of age  | On open skin wounds                  |  |  |
| with eyes, rinse eye:                      | od uct keep out of eyes, ears and<br>s thoroughly with water.           |                                      |  |  |
| Stopuse and aska<br>serious condition      | doctorifimitation or rash occurs  | . These may be signs of a            |  |  |
| Keepout of reach of<br>Control Centerright | of children. If swallowed, get med<br>away.                             | ilical helpor contact a Poison       |  |  |
| Directions                                 | 19 <sup>15</sup> 19 1919 19 19 19                                       |                                      |  |  |
|  | ct on hands to cover all surfaces.<br>Inder 6 years of age when using t |                                      |  |  |
| Other Information                          | Store between 15-30C (59-   | Avoid freezing or<br>heat>40C (104F) |  |  |

# Alcohol Antiseptic 80% Topical Solution

# Hand Sanitizer Non-Sterile Solution



| Drug Facta                                  |   |                                      |
|---|---|--------------------------------------|
| Active Ingredients                          |   | Purpose                              |
| Alcohol 79%                                 |   | Antiseptic                           |
| Use(s):                                     |   |                                      |
| Hand sanifizer to hel<br>when soap and wate | lp reduce bacteriathat potentially<br>er are not available.             | can cause disease. Foruse            |
| Warnings:                                   |   |                                      |
| Forexternaluse or                           | ily. Flammable. Keep away from  | nheatorflame                         |
| Do Not Use: In                              | children under 2 months of age  | On open skin wounds                  |
| with eyes, rinse eyes                       | od uct keep out of eyes, ears and<br>s thoroughly with water.           |                                      |
| Stop use and aska<br>serious condition      | doctorifinitation or rash occurs  | . These may be signs of a            |
| Keepout of reach of<br>Control Centerright  | of children. If swallowed, get med<br>away.                             | dical help or contact a Poison       |
| Directions                                  |   | AND THE PARTY AND                    |
|   | ct on hands to cover all surfaces.<br>Inder 6 years of age when using t |                                      |
| Other Information                           | Store between 15-30C (59-<br>  86F)                                     | Avoid freezing or<br>heat>40C (104F) |

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

| HAND SANIT                | I7FD                     |  |            |                    |              |                    |  |
|---------------------------|--------------------------|--|------------|--------------------|--------------|--------------------|--|
|                           |                          |  |            |                    |              |                    |  |
| alcohol liquid            |                          |  |            |                    |              |                    |  |
|                           |                          |  |            |                    |              |                    |  |
| Product Informa           | ition                    |  |            |                    |              |                    |  |
| Product Type              |                          | HUMAN OTC DRUG Item Code (Source) NDC:74363-001      |            |                    |              | NDC:74363-001      |  |
| Route of Administr        | ation                    | TOPICAL  |            |                    |              |                    |  |
| Koute of Auministi        | uuun                     | TOTIONE  |            |                    |              |                    |  |
|                           |                          |  |            |                    |              |                    |  |
| Active Ingredier          | t/Activo Moi             | n tx   |            |                    |              |                    |  |
| Acuve ingreuier           |                          | •  |            | <b>.</b> .         |              |                    |  |
|                           | 0                        | lient Name   |            |                    | of Strength  | Strength           |  |
| ALCOHOL (UNII: 3KS        | 9958V90M) (ALC           | COHOL - UNII:3K9958V90M)                             |            | ALCOHO             | DL           | 80 mL in 100 mL    |  |
|                           |                          |  |            |                    |              |                    |  |
|                           |                          |  |            |                    |              |                    |  |
| Inactive Ingredi          | ents                     |  |            |                    |              |                    |  |
|                           | Ing                      | gredient Name  |            |                    |              | Strength           |  |
| GLYCERIN (UNII: PD        | C6A3C0OX)                |  |            | 1.45 mL in 100 mL  |              |                    |  |
| HYDRO GEN PERO X          | I <b>DE</b> (UNII: BBX06 | 0 AN9 V)   |            | 0.125 mL in 100 mL |              |                    |  |
| WATER (UNII: 059QF        | 0KO0R)                   |  |            |                    |              |                    |  |
|                           |                          |  |            |                    |              |                    |  |
|                           |                          |  |            |                    |              |                    |  |
| Packaging                 |                          |  |            |                    |              |                    |  |
| # Item Code               |                          | Package Description                                  |            | Marketin           | g Start Date | Marketing End Date |  |
|                           |                          | TLE; Type 0: Not a Combination                       |            | 04/01/2020         | •            |                    |  |
|                           |                          | BOTTLE; Type 0: Not a Combination Product 04/01/2020 |            |                    |              |                    |  |
|                           |                          | TLE; Type 0: Not a Combination                       |            | 04/01/2020         | )            |                    |  |
|                           |                          | TTLE; Type 0: Not a Combination                      |            |                    |              |                    |  |
| 5 NDC:74363-001-05        | 100 mL in 1 BO           | TLE; Type 0: Not a Combinatior                       | n Product  | 04/01/2020         | )            |                    |  |
| 6 NDC:74363-001-06        | 500 mL in 1 BO           | TTLE; Type 0: Not a Combination                      | n Product  | 04/01/2020         | )            |                    |  |
| 7 NDC:74363-001-07        | 750 mL in 1 BO           | TTLE; Type 0: Not a Combinatior                      | n Product  | 04/01/2020         | )            |                    |  |
| 8 NDC:74363-001-08        | 1000 mL in 1 BC          | OTTLE; Type 0: Not a Combination                     | n Product  | 04/01/2020         | )            |                    |  |
| <b>o</b> NDC:/4363-001-08 | 1000 mL in 1 BC          | TILE; Type U: Not a Combinatio                       | on Product | 04/01/2020         | )            |                    |  |
|                           |                          |  |            |                    |              |                    |  |

| Marketing Information                    |  |   |  |  |
|--|--|---|--|--|
| Application Number or Monograph Citation | Marketing Start Date                     | Marketing End Date  |  |  |
| part333A                                 | 04/01/2020                               |   |  |  |
|  | Application Number or Monograph Citation | Application Number or Monograph Citation Marketing Start Date |  |  |

# Labeler - Washington State University (041485301)

| Establishment               |         |           |                            |  |  |
|-----------------------------|---------|-----------|----------------------------|--|--|
| Name                        | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Washington State University |         | 041485301 | manufacture(74363-001)     |  |  |

Revised: 3/2020

Washington State University