

## **HAND SANITIZER- alcohol gel**

### **D3W Industries Inc.**

*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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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 70% 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**

Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Vera Barbadosensis Leaf, PEG-6, PEG-12 Dimethicone, Water, May contain Fragrance

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



128 fl oz / 3785 mL

D3W Industries, Inc.  
Michigan, USA



# *Hand Sanitizer*

64 fl oz / 1893 mL

D3W Industries, Inc.  
Michigan, USA



# *Hand Sanitizer*

32 fl oz / 946 mL

D3W Industries, Inc.  
Michigan, USA





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# *Hand Sanitizer*

16 fl oz / 473 mL

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D3W Industries, Inc.  
Michigan, USA

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# Hand Sanitizer

8 fl oz / 237 mL

D3W Industries, Inc.  
Michigan, USA

## Drug Facts:

**Active Ingredients**  
Ethyl Alcohol 70% v/v.....Antiseptic  
**Purpose**  
Uses For external use only. For use when soap and water not available to disinfect hands.

**Warnings:** Flammable. Keep away from fire or flame.  
**When using this product:** Do not use in eyes, ears and mouth. In case of contact with eyes, rinse with water. If swallowed, get medical help or contact a Poison Control Center. Stop use and ask a doctor if: Irritation and redness develop and persist. Keep out of reach of children.

**Directions:** Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised when using product.

**Other Information:** Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).

**Inactive Ingredients:** Acrylates/Vinyl Isodecanoate Crosspolymer,, Aloe Barbadosensis Leaf, PEG-6, PEG-12 Dimethicone, Water, May contain fragrance.

Made in the USA



# Hand Sanitizer

2 fl oz / 59 mL

D3W Industries, Inc.  
Michigan, USA

## Drug Facts:

**Active Ingredients**  
Ethyl Alcohol 70% v/v.....Antiseptic  
**Purpose**  
Uses For external use only. For use when soap and water not available to disinfect hands.

**Warnings:** Flammable. Keep away from fire or flame.  
**When using this product:** Do not use in eyes, ears and mouth. In case of contact with eyes, rinse with water. If swallowed, get medical help or contact a Poison Control Center. Stop use and ask a doctor if: Irritation and redness develop and persist. Keep out of reach of children.

**Directions:** Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised when using product.

**Other Information:** Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).

**Inactive Ingredients:** Acrylates/Vinyl Isodecanoate Crosspolymer,, Aloe Barbadosensis Leaf, PEG-6, PEG-12 Dimethicone, Water, May contain fragrance.

Made in the USA





# Hand Sanitizer

4 fl oz / 119 mL

D3W Industries, Inc.  
Michigan, USA

**Drug Facts:**

**Active Ingredients**

Ethyl Alcohol 70% v/v.....Antiseptic  
Uses for external use only. For use when soap and water not available to disinfect hands.

**Purpose**

**Warnings:** Flammable. Keep away from fire or flame.

**When using this product:** Do not use in eyes, ears and mouth. In case of contact with eyes, rinse with water. If swallowed, get medical help or contact a Poison Control Center. Stop use and ask a doctor if: Irritation and redness develop and persist. Keep out of reach of children.

**Directions:** Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised when using product.

**Other Information:** Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F).

**Inactive Ingredients:** Acrylates/Vinyl Isodecanoate Crosspolymer,, Aloe Barbadosis Leaf, PEG-6, PEG-12 Dimethicone, Water, May contain fragrance.

Made in the USA 



# Hand Sanitizer

640 fl oz / 18927 mL

D3W Industries, Inc.  
Michigan, USA

18927 mL NDC: 80710-213-60

**HAND SANITIZER**

alcohol gel

### Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:80710-213(NDC:66902-343) |
| <b>Route of Administration</b> | TOPICAL        |                           |                              |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| <b>Ingredient Name</b>            | <b>Strength</b> |
|-----------------------------------|-----------------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |                 |

### Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                    | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---------------------------------------------------------------|-----------------------------|---------------------------|
| 1        | NDC:80710-213-64 | 00 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/06/2020                  |                           |

### Marketing Information

| <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                                        | 03/30/2020                  |                           |

**Labeler** - D3W Industries Inc. (106099086)

### Establishment

| <b>Name</b>         | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|---------------------|----------------|---------------|----------------------------|
| D3W Industries Inc. |                | 106099086     | repack(80710-213)          |

Revised: 1/2023

D3W Industries Inc.