

## **JUST HAND SANITIZER- alcohol liquid**

**Studio 320 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 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

3790 mL NDC: 78065-2021-1

**Just Hand Sanitizer™**  
**ANTISEPTIC HAND RUB**

**80% ALCOHOL**

**MADE IN USA**  
**1 GALLON (3785 ML)**

| Drug Facts  |                |
|---|----------------|
| <b>Active Ingredient</b>  | <b>Purpose</b> |
| Ethyl Alcohol 80% v/v   | Antiseptic     |
| <b>Use</b> • Health care personnel hand rub to help reduce bacteria that potentially can cause disease.       |                |
| <b>Warnings</b>   |                |
| Flammable. Keep away from fire or flame.  |                |
| For external use only   |                |
| When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. |                |
| Stop use and ask a doctor if irritation or rash appears and lasts   |                |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.  |                |
| <b>Directions</b> • Put enough products in your palm to cover hands and rub hands together briskly until dry  |                |
| • Children under 6 years of age should be supervised when using when using this product                       |                |
| <b>Other Information</b> • Store between 15-30C (59-86F)  |                |
| • Avoid freezing and excessive heat above 40C (104F)  |                |
| <b>Inactive Ingredients</b> Glycerin, Hydrogen Peroxide, Distilled Water USP                                  |                |

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To See Lab Results

240 mL NDC: 78065-2021-2

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**Just Hand  
Sanitizer™**

**ANTISEPTIC  
HAND RUB**



**MADE IN USA**  
**8 FL OZ (240 ML)**

#### Drug Facts

| Active Ingredient   | Purpose    |
|---|------------|
| Ethyl Alcohol 80% v/v   | Antiseptic |
| <b>Use</b> • Health care personnel hand rub to help reduce bacteria that potentially can cause disease.   |            |
| <b>Warnings</b><br>Flammable. Keep away from fire or flame.   |            |
| For external use only   |            |
| When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.   |            |
| Stop use and ask a doctor if irritation or rash appears and lasts   |            |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.  |            |
| <b>Directions</b> • Put enough products in your palm to cover hands and rub hands together briskly until dry<br>• Children under 6 years of age should be supervised when using when using this product |            |
| <b>Other Information</b> • Store between 15-30C (59-86F)<br>• Avoid freezing and excessive heat above 40C (104F)  |            |
| <b>Inactive Ingredients</b> Glycerin, Hydrogen Peroxide, Distilled Water USP  |            |

60 mL NDC: 78065-2021-3

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**Just Hand  
Sanitizer™**

**ANTISEPTIC  
HAND RUB**



**MADE IN USA**  
**2 FL OZ (60 ML)**

#### Drug Facts

| Active Ingredient   | Purpose    |
|---|------------|
| Ethyl Alcohol 80% v/v   | Antiseptic |
| <b>Use</b> • Health care personnel hand rub to help reduce bacteria that potentially can cause disease.   |            |
| <b>Warnings</b><br>Flammable. Keep away from fire or flame.   |            |
| For external use only   |            |
| When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.   |            |
| Stop use and ask a doctor if irritation or rash appears and lasts   |            |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.  |            |
| <b>Directions</b> • Put enough products in your palm to cover hands and rub hands together briskly until dry<br>• Children under 6 years of age should be supervised when using when using this product |            |
| <b>Other Information</b> • Store between 15-30C (59-86F)<br>• Avoid freezing and excessive heat above 40C (104F)  |            |
| <b>Inactive Ingredients</b> Glycerin, Hydrogen Peroxide, Distilled Water USP  |            |

500 mL NDC: 78065-2021-4

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**Just Hand  
Sanitizer™**

**ANTISEPTIC  
HAND RUB**



**MADE IN USA**  
**17 FL OZ (500 ML)**

### Drug Facts

| Active Ingredient          | Purpose    |
|----------------------------|------------|
| Ethyl Alcohol 80% v/v..... | Antiseptic |

**Use** • Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

### Warnings

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

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** • Put enough products in your palm to cover hands and rub hands together briskly until dry  
• Children under 6 years of age should be supervised when using when using this product

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

**Inactive Ingredients** Glycerin, Hydrogen Peroxide, Distilled Water USP

## JUST HAND SANITIZER

alcohol liquid

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:78065-2021 |
| Route of Administration | TOPICAL        |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 80 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name                      | Strength           |
|--------------------------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX)          | 1.45 mL in 100 mL  |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0K00R)             |                    |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|   | NDC:78065 |                     |                      |                    |

|   |                  |   |            |  |
|---|------------------|---|------------|--|
| 1 | NDC:78065-2021-1 | 3790 mL in 1 BOTTLE; Type 0: Not a Combination Product            | 03/30/2020 |  |
| 2 | NDC:78065-2021-2 | 240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020 |  |
| 3 | NDC:78065-2021-3 | 60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product  | 03/30/2020 |  |
| 4 | NDC:78065-2021-4 | 500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product      | 03/30/2020 |  |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A                                 | 03/30/2020           |                    |

**Labeler** - Studio 320 Inc (066376564)

| Establishment |         |           |                         |
|---------------|---------|-----------|-------------------------|
| Name          | Address | ID/FEI    | Business Operations     |
| Studio 320    |         | 066376564 | manufacture(78065-2021) |