

## **HAND SANITIZER- isopropyl alcohol gel**

### **Lustrous Metal Coatings 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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% 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.

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**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)

glycerin, hydrogen peroxide, purified water USP, polyacrylate crosspolymer-6

**Package Label - Principal Display Panel**

## **Drug Facts**

### **Active ingredient(s)**

### **Purpose**

Isopropyl alcohol 75% v/v.....Antiseptic

### **Use(s)**

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

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### **Inactive ingredients**

glycerin, hydrogen peroxide, polyacrylate crosspolymer-6, purified water USP

# LIQUID

## Hand Sanitizer Gel

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**



**[www.ShopLiquid.com](http://www.ShopLiquid.com)**

**2.0 FL OZ (59 mL)**

59 ml NDC 75582-220-07

|  |   |
|--|---|
| <b>Drug Facts</b>  | <b>Drug Facts (continued)</b>   |
| <b>Active ingredient(s)</b><br>Isopropyl alcohol, 75% v/v.....   | <b>Purpose</b><br>Antiseptic  |
| <b>Use(s)</b><br>Health care personnel hand rub to help reduce bacteria that potentially can cause disease.  | <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>Warnings</b><br>For external use only. Flammable. Keep away from heat or flame.<br><b>Do not use</b><br>in children less than 2 months<br>on open skin wounds | <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.<br><b>Directions</b><br>Place enough product on hands to cover all surfaces. Rub hands together until dry.<br>Supervise children under 6 years of age when using this product to avoid swallowing. |

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## Hand Sanitizer Gel

Kills 99.99% of Most Germs

Contains 75% Isopropyl Alcohol



[www.ShopLiquid.com](http://www.ShopLiquid.com)

68 FL OZ (2011 mL)

2011 ml NDC 75582-220-05

|   |
|---|
| <b>Drug Facts (continued)</b>   |
| <b>Other Information</b><br>Store between 15-30C (59-86F)<br>Avoid freezing and excessive heat above 40C (104F) |
| <b>Inactive ingredients</b><br>glycerin, hydrogen peroxide, polyacrylate crosspolymer-6, purified water USP     |

**Drug Facts**

| <b>Active ingredient(s)</b>    | <b>Purpose</b> |
|--------------------------------|----------------|
| Isopropyl alcohol 75% v/v..... | Antiseptic     |

**Use(s)**

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

**Warnings**

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**Keep away from heat or flame**

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**Other Information**

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**Inactive ingredients**

glycerin, hydrogen peroxide, polyacrylate crosspolymer-6, purified water USP

237 ml NDC 75582-220-02

**Drug Facts**

| <b>Active ingredient(s)</b>    | <b>Purpose</b> |
|--------------------------------|----------------|
| Isopropyl alcohol 75% v/v..... | Antiseptic     |

**Use(s)**

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

## ***Warnings***

**For external use only. Flammable.  
Keep away from heat or flame**

### **Do not use**

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- Store between 15-30C (59-86F)
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## ***Inactive ingredients***

glycerin, hydrogen peroxide, polyacrylate crosspolymer-6, purified water USP

3784 ml NDC 75582-220-06

# **TIPOUTD**



# **Hand Sanitizer Gel**

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**



**[www.ShopLiquid.com](http://www.ShopLiquid.com)**

**1 Gallon (3.784 Liter)**



1 GALLON (3.785 LITER)

3784 ml NDC 75582-220-06

# LIQUID

**Hand Sanitizer Gel**

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**



[www.ShopLiquid.com](http://www.ShopLiquid.com)

32 FL OZ (946 mL)

946 ml NDC 75582-

**LIQUID**

**Hand Sanitizer Gel**

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**





**[www.ShopLiquid.com](http://www.ShopLiquid.com)**

**16 FL OZ (473 mL)**

220-04

473 ml NDC

# LIQUID

## Hand Sanitizer Gel

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**



**[www.ShopLiquid.com](http://www.ShopLiquid.com)**

**8 FL OZ (237 mL)**

75582-220-03

237 ml NDC

# LIQUID

## Hand Sanitizer Gel

**Kills 99.99% of  
Most Germs**

**Contains 75%  
Isopropyl Alcohol**



**[www.ShopLiquid.com](http://www.ShopLiquid.com)**

**4.0 FL OZ (118 mL)**

75582-220-02

118 ml NDC

**Drug Facts**

| <b>Active ingredient(s)</b>    | <b>Purpose</b> |
|--------------------------------|----------------|
| Isopropyl alcohol 75% v/v..... | Antiseptic     |

**Use(s)**

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

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|--------------------------------|----------------|
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|  |                |
|--|----------------|
| <b>Drug Facts</b>  |                |
| <b>Active ingredient(s)</b>  | <b>Purpose</b> |
| Isopropyl alcohol 75% v/v.....   | Antiseptic     |
| <b>Use(s)</b>  |                |
| Health care personnel hand rub to help reduce bacteria that potentially can cause disease.   |                |
| <b>Warnings</b>  |                |
| For external use only. Flammable.<br>Keep away from heat or flame  |                |
| <b>Do not use</b>  |                |
| <ul style="list-style-type: none"> <li>· in children less than 2 months</li> <li>· on open skin wounds</li> </ul>  |                |
| <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>  |                |
| <ul style="list-style-type: none"> <li>· Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>· Supervise children under 6 years fo age when using this product to avoid swallowing.</li> </ul> |                |
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| <b>Inactive ingredients</b>  |                |
| glycerin, hydrogen peroxide, polyacrylate crosspolymer-6, purified water USP   |                |

75582-220-03  
75582-220-04

946 ml NDC

**HAND SANITIZER**

isopropyl alcohol gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:75582-220 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |



**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL |

**Inactive Ingredients**

| Ingredient Name  | Strength           |
|--|--------------------|
| AMMONIUM ACRYLO YLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9) | 0.67 mL in 100 mL  |
| GLYCERIN (UNII: PDC6A3C0OX)  | 0.2 mL in 100 mL   |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V)   | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0KO0R)   |                    |

**Packaging**

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75582-220-01 | 118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product     | 03/30/2020           |                    |
| 2 | NDC:75582-220-02 | 237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product     | 03/30/2020           |                    |
| 3 | NDC:75582-220-03 | 473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product     | 03/30/2020           |                    |
| 4 | NDC:75582-220-04 | 946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product     | 03/30/2020           |                    |
| 5 | NDC:75582-220-05 | 2011 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product    | 03/30/2020           |                    |
| 6 | NDC:75582-220-06 | 3784 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020           |                    |
| 7 | NDC:75582-220-07 | 59 mL in 1 BOTTLE, PUMP; 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 mono graph not final | part333A                                 | 03/30/2020           |                    |

**Labeler** - Lustrous Metal Coatings Inc (604719070)**Registrant** - Lustrous Metal Coatings Inc (604719070)**Establishment**

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Lustrous Metal Coatings Inc |         | 604719070 | manufacture(75582-220) |