

**LK CLEAN GEL (ETHANOL)- alcohol gel**  
**Venice Cosmetic**

*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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**LK clean gel (Ethanol)**

**Active ingredient**

Ethanol 70%

**Uses**

Hand sanitizer for decreasing bacteria on skin

**Purpose**

Antibacterial

**Warnings**

For external use only

Do not use if you are allergic to any of the ingredients

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. avoid contact with broken, irritated, or itching skin. Do not puncture or incinerate.

Stop use and ask a doctor if irritation or redness develops and condition persists for more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

**Directions**

Take appropriate amount onto your hand and spread it all the way to fingertips. Rub the contents until it dries

**Inactive ingredients**

Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerin, Aloe Extract

**Keep out of reach of children**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**LK Clean gel (Ethanol)**

# Hi-Tech Bio HAND SANITIZER

QUASI-DRUG

LK clean gel (Ethanol)



Ethanol 70%  
50ml (1.69 FL.OZ)

# Hi-Tech Bio HAND SANITIZER

QUASI-DRUG

LK clean gel (Ethanol)



Ethanol 70%  
100ml (3.38 FL.OZ)

LK clean gel (Ethanol)

| Drug Facts  |               |
|---|---------------|
| Active Ingredient   | Purpose       |
| Ethanol (70%)   | Antibacterial |
| <b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |               |
| <b>Warnings</b><br>For external use only. Flammable. Keep away from heat or flame.  |               |
| <b>Do not use</b> <ul style="list-style-type: none"> <li>if you are allergic to any of the ingredients</li> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>   |               |
| <b>When using this product</b> avoid contact with 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 (1-800-222-1222) right away.  |               |
| <b>If pregnant or breast-feeding,</b> ask a health professional before use.   |               |
| <b>Directions</b> <ul style="list-style-type: none"> <li>Take appropriate amount onto your hand and spread it all the way to fingertips. Rub hands together until dry.</li> <li>Supervise Children under 6 years of age when using this product to avoid swallowing.</li> </ul> |               |
| <b>Other Information</b> <ul style="list-style-type: none"> <li>Store at temperature between 59°F - 86°F (15°C - 30°C)</li> <li>May discolor certain fabrics or surfaces</li> <li>Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>                               |               |
| <b>Inactive Ingredients</b><br>Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerin, Aloe extract   |               |

Manufactured by: Venice Cosmetic. 242, Namdong-daero, Namdong-gu, Incheon, Korea



MADE IN KOREA

LK clean gel (Ethanol)

| Drug Facts  |               |
|---|---------------|
| Active Ingredient   | Purpose       |
| Ethanol (70%)   | Antibacterial |
| <b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |               |
| <b>Warnings</b><br>For external use only. Flammable. Keep away from heat or flame.  |               |
| <b>Do not use</b> <ul style="list-style-type: none"> <li>if you are allergic to any of the ingredients</li> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>   |               |
| <b>When using this product</b> avoid contact with 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.   |               |
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Manufactured by: Venice Cosmetic. 242, Namdong-daero, Namdong-gu, Incheon, Korea



MADE IN KOREA

# Hi-Tech Bio HAND SANITIZER

QUASI-DRUG

LK clean gel (Ethanol)



Ethanol 70%

250ml (8.45 FL.OZ)

# Hi-Tech Bio HAND SANITIZER

QUASI-DRUG

LK clean gel (Ethanol)



Ethanol 70%

500ml (16.9 FL.OZ)

LK clean gel (Ethanol)

| Drug Facts  |                                 |
|---|---------------------------------|
| <b>Active Ingredient</b><br>Ethanol (70%)   | <b>Purpose</b><br>Antibacterial |
| <b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |                                 |
| <b>Warnings</b><br>For external use only. Flammable. Keep away from heat or flame.  |                                 |
| <b>Do not use</b> <ul style="list-style-type: none"> <li>• if you are allergic to any of the ingredients</li> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>   |                                 |
| <b>When using this product</b> avoid contact with 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 (1-800-222-1222) right away.  |                                 |
| <b>If pregnant or breast-feeding,</b> ask a health professional before use.   |                                 |
| <b>Directions</b> <ul style="list-style-type: none"> <li>• Take appropriate amount onto your hand and spread it all the way to fingertips. Rub hands together until dry.</li> <li>• Supervise Children under 6 years of age when using this product to avoid swallowing.</li> </ul> |                                 |
| <b>Other Information</b> <ul style="list-style-type: none"> <li>• Store at temperature between 59°F - 86°F (15°C - 30°C)</li> <li>• May discolor certain fabrics or surfaces</li> <li>• Avoid freezing and excessive heat above 104°F (40°C)</li> </ul>                             |                                 |
| <b>Inactive Ingredients</b><br>Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerin, Aloe extract   |                                 |

Manufactured by: Venice Cosmetic. 242, Namdong-daero, Namdong-gu, Incheon, Korea



PUMP:OTHER



MADE IN KOREA

LK clean gel (Ethanol)

| Drug Facts  |                                 |
|---|---------------------------------|
| <b>Active Ingredient</b><br>Ethanol (70%)   | <b>Purpose</b><br>Antibacterial |
| <b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.   |                                 |
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| <b>Do not use</b> <ul style="list-style-type: none"> <li>• if you are allergic to any of the ingredients</li> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>   |                                 |
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| <b>Inactive Ingredients</b><br>Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerin, Aloe extract   |                                 |

Manufactured by: Venice Cosmetic. 242, Namdong-daero, Namdong-gu, Incheon, Korea



PUMP:OTHER



MADE IN KOREA

## LK CLEAN GEL (ETHANOL)

alcohol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:74488-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

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

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX)                                |          |
| TROLAMINE (UNII: 9O3K93S3TK)                               |          |
| WATER (UNII: 059QF0KO0R)                                   |          |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                        |          |
| ALOE (UNII: V5VD430YW9)                                    |          |

**Packaging**

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74488-002-01 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/09/2020           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E                                 | 04/09/2020           |                    |

**LK CLEAN GEL (ETHANOL)**

alcohol gel

**Product Information**

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:74488-007 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX)                                |          |
| TROLAMINE (UNII: 9O3K93S3TK)                               |          |
| WATER (UNII: 059QF0KO0R)                                   |          |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                        |          |
| ALOE (UNII: V5VD430YW9)                                    |          |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

|                              |   |   |                           |  |
|------------------------------|---|---|---------------------------|--|
| 1                            | NDC:74488-007-01                                | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/09/2020                |  |
| <b>Marketing Information</b> |   |   |                           |  |
| <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      | part333E  | 04/09/2020  |                           |  |

|  |   |  |                             |                           |
|--|---|--|-----------------------------|---------------------------|
| <b>LK CLEAN GEL (ETHANOL)</b>          |   |  |                             |                           |
| alcohol gel                            |   |  |                             |                           |
| <b>Product Information</b>             |   |  |                             |                           |
| <b>Product Type</b>                    | HUMAN OTC DRUG  | <b>Item Code (Source)</b>                            | NDC:74488-006               |                           |
| <b>Route of Administration</b>         | TOPICAL   |  |                             |                           |
| <b>Active Ingredient/Active Moiety</b> |   |  |                             |                           |
|  | <b>Ingredient Name</b>                                    | <b>Basis of Strength</b>                             | <b>Strength</b>             |                           |
|  | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)    | ALCOHOL  | 70 mL in 100 mL             |                           |
| <b>Inactive Ingredients</b>            |   |  |                             |                           |
|  | <b>Ingredient Name</b>                                    | <b>Strength</b>                                      |                             |                           |
|  | GLYCERIN (UNII: PDC6A3C0OX)                               |  |                             |                           |
|  | TROLAMINE (UNII: 9O3K93S3TK)                              |  |                             |                           |
|  | WATER (UNII: 059QF0KO0R)                                  |  |                             |                           |
|  | CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |  |                             |                           |
|  | PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                       |  |                             |                           |
|  | ALOE (UNII: V5VD430YW9)                                   |  |                             |                           |
| <b>Packaging</b>                       |   |  |                             |                           |
| <b>#</b>                               | <b>Item Code</b>  | <b>Package Description</b>                           | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1                                      | NDC:74488-006-01  | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/09/2020                  |                           |
| <b>Marketing Information</b>           |   |  |                             |                           |
| <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                | part333E  | 04/09/2020   |                             |                           |

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>LK CLEAN GEL (ETHANOL)</b> |  |  |  |  |
| alcohol gel                   |  |  |  |  |
| <b>Product Information</b>    |  |  |  |  |

|  |   |   |                             |                           |
|--|---|---|-----------------------------|---------------------------|
| <b>Product Type</b>  | HUMAN OTC DRUG                                  | <b>Item Code (Source)</b>                             | NDC:74488-008               |                           |
| <b>Route of Administration</b>                             | TOPICAL   |   |                             |                           |
| <b>Active Ingredient/Active Moiety</b>                     |   |   |                             |                           |
| <b>Ingredient Name</b>                                     |   | <b>Basis of Strength</b>                              | <b>Strength</b>             |                           |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)     |   | ALCOHOL   | 70 mL in 100 mL             |                           |
| <b>Inactive Ingredients</b>                                |   |   |                             |                           |
| <b>Ingredient Name</b>                                     |   |   | <b>Strength</b>             |                           |
| GLYCERIN (UNII: PDC6A3C0OX)                                |   |   |                             |                           |
| TROLAMINE (UNII: 9O3K93S3TK)                               |   |   |                             |                           |
| WATER (UNII: 059QF0K00R)                                   |   |   |                             |                           |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |   |   |                             |                           |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                        |   |   |                             |                           |
| ALOE (UNII: V5VD430YW9)                                    |   |   |                             |                           |
| <b>Packaging</b>   |   |   |                             |                           |
| <b>#</b>   | <b>Item Code</b>                                | <b>Package Description</b>                            | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1  | NDC:74488-008-01                                | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/09/2020                  |                           |
| <b>Marketing Information</b>                               |   |   |                             |                           |
| <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                                    | part333E  | 04/09/2020  |                             |                           |

**Labeler** - Venice Cosmetic (695047082)

### Establishment

| Name            | Address | ID/FEI    | Business Operations                                     |
|-----------------|---------|-----------|---|
| Venice Cosmetic |         | 695047082 | manufacture(74488-002, 74488-006, 74488-007, 74488-008) |

Revised: 4/2020

Venice Cosmetic