### CLEAN AND HAND- alcohol gel Enprani Co., Ltd.

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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### ACTIVE INGREDIENT

Active ingredients: ALCOHOL 62% w/w

### INACTIVE INGREDIENT

Inactive ingredients:

Water, Butylene Glycol, Carbomer

### **PURPOSE**

Purpose: ANTISEPTIC

### **WARNINGS**

Warnings:

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

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Do not use

- in children less than 2 months of age
- on open skin wounds

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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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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

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

### Uses

Uses:

Hand sanitizer to help reduce bacteria that potentially can cause disease.

### **Directions**

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

### Other information

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

### PACKAGE LABEL - CLEAN & HAND GEL 55mL





PACKAGE LABEL - CLEAN & HAND GEL 250mL



NO FRAGRANCE

의약외품

### Hand Sanitizer

Mild & Moist

Ethanol

- Kills 99.9% Germs
- Rinese free & Non sticky 250 ml / 8.45 fl. oz.

HOLIKA HOLIKA

## **Drug Facts Active ingredients** Purpose ALCOHOL 62% w/w ····· Hand sanitizer to help reduce bacteria that potentially can cause disease. 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. 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 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)

## Inactive ingredients Water, Butylene Glycol, Carbomer

Distributor: ENPRANI CO., LTD.
88, Chukhang-daero 296 beon-gil,
Jung-gu, Incheon, Korea
Manufacturer Opseve KOREA Co.,Ltd.
364 Seunggicheon-ro, Namdong-gu,
Incheon, Incheon 21628, Korea
MADE IN KOREA (1477)
www.holikaholika.co.kr



PACKAGE LABEL - CLEAN & HAND GEL 500mL



NO FRAGRANCE

의약외품

### Hand Sanitizer

Mild & Moist

**62**% Ethanol

- Kills 99.9% Germs
- Rinese free & Non sticky

500 ml / 16.90 fl. oz.

HOLIKA HOLIKA

### **Drug Facts** Active ingredients Purpose ALCOHOL 62% w/w ANTISEPTIC

Hand sanitizer to help reduce bacteria that potentially can cause disease

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

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.

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 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients Water, Butylene Glycol, Carbomer

Distributor: ENPRANI CO., LTD. 88, Chukhang-daero 296 beon-gil, Jung-gu, Incheon, Korea

Manufacturer: Opseve KOREA Co., Ltd. 364 Seunggicheon-ro, Namdong-gu, Incheon, Incheon 21628, Korea MADE IN KOREA (1428) www.holikaholika.co.kr



### **CLEAN AND HAND**

alcohol gel

### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:69551-051

**Route of Administration** TOPICAL

### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) 62 g in 100 mL ALCOHOL

### **Inactive Ingredients**

| Ingredient Name   | Strength |  |
|---|----------|--|
| Water (UNII: 059QF0KO0R)                                      |          |  |
| Butylene Glycol (UNII: 3XUS85K0RA)                            |          |  |
| CADROMED HOMODOL VMED LINSDECIEIED TVDE (LINII) 0.45MM20.7EC) |          |  |

### **Packaging**

| # | Item Code            | Package Description   | Marketing Start Date | Marketing End<br>Date |
|---|----------------------|---|----------------------|-----------------------|
| 1 | NDC:69551-051-<br>01 | 55 mL in 1 BOTTLE; Type 0: Not a Combination Product        | 04/01/2020           |                       |
| 2 | NDC:69551-051-<br>02 | 250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/01/2020           |                       |
| 3 | NDC:69551-051-<br>03 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/01/2020           |                       |

| Marketing Information   |  |                      |                    |  |  |  |  |
|-------------------------|--|----------------------|--------------------|--|--|--|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |  |  |
| OTC monograph not final | part333E                                 | 04/01/2020           |                    |  |  |  |  |
|                         |  |                      |                    |  |  |  |  |

# **Labeler -** Enprani Co., Ltd. (631100112)

## Registrant - Enprani Co., Ltd. (631100112)

| Establishment         |         |           |                         |  |  |  |  |
|-----------------------|---------|-----------|-------------------------|--|--|--|--|
| Name                  | Address | ID/FEI    | Business Operations     |  |  |  |  |
| Opseve KOREA Co.,Ltd. |         | 690048629 | manufacture (69551-051) |  |  |  |  |

Revised: 4/2020 Enprani Co., Ltd.