# DEVOLVER PREMIUM GEL- alcohol gel Devolver Cosmetics 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**

Ethyl Alcohol 70%

### **Purpose**

Antiseptic

### Use

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**

Wet hands thoroughly with product and allow to dry without wiping.

For children under 6, use only under adult supervision.

### Other information

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

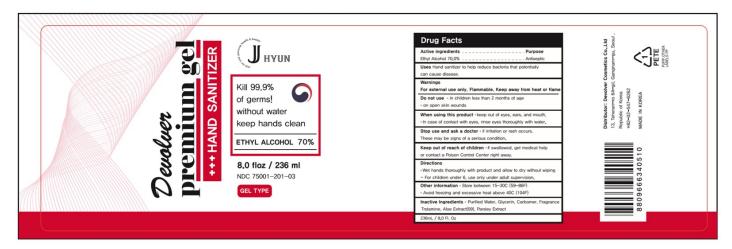
### **Inactive ingredients**

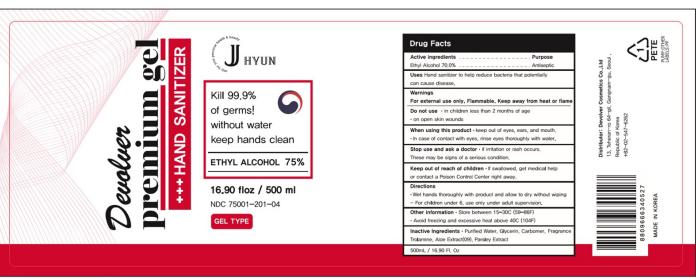
Purified Water, Glycerin, Carbomer, Fragrance, Trolamine, Aleo Extract(09), Parsley Extract

# **Package Label**













Kill 99,9% of germs! without water keep hands clean

ETHYL ALCOHOL 70%

1 GAL (3.78 L)

NDC 75001-201-05

**GEL TYPE** 

### **Drug Facts**

Uses 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,

- · Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision.

Other information · Store between 15-30C (59-86F)

· Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients -Ethanol, Purified Water, Glycerin, Carbomer, Orange Oil, Trolamine, Aloe Extract(09), Parsley Extract

500mL / 16.90 Fl. Oz



13, Teheran-ro 64-gil, Gangnam-gu, Seoul , Distributor: Devolver Cosmetics Co., Ltd



Kill 99.9% of germs! without water keep hands clean

ETHYL ALCOHOL 70%

4.06 floz / 120 ml

**GEL TYPE** 

### **Drug Facts**

Active ingredients . . . . . . . . . Purpose Ethyl Alcohol 70,0% . . . . . . . . . . . . . . Antiseptic

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

### Warnings

For external use only, Flammable, Keep away from heat or flam

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

· Wet hands thoroughly with product and allow to dry without wiping

- For children under 6, use only under adult supervision,

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

Inactive Ingredients · Purified Water, Glycerin, Carbomer, Fragrance

Trolamine, Aloe Extract(09), Parsley Extract

120 ml / 4,06 FL,Oz

Distributor: Devolver Cosmetics Co.,Ltd 13, Teheran-ro 64-gil, Gangnam-gu, Seoul Republic of Korea +82-02-547-6262 A PETE MADE IN KOREA





# \*\*\* HAND SANITIZER



Kill 99.9% of germs! without water keep hands clean

ETHYL ALCOHOL 70%

11,83 floz / 350ml

GEL TYPE

### **Drug Facts**

Active ingredients . . . . . . . . . . Purpose

Ethyl Alcohol 70,0%

Uses Hand sanitizer to help reduce bacteria that potentially

For external use only, Flammable, Keep away from heat or flam

Do not use · in children less than 2 months of age

When using this product · keep out of eyes, ears, and mouth.

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  $\cdot$  If swallowed, get medical help or contact a Poison Control Center right away.

· Wet hands thoroughly with product and allow to dry without wiping - For children under 6, use only under adult supervision.

Other information · Store between 15-30C (59-86F)

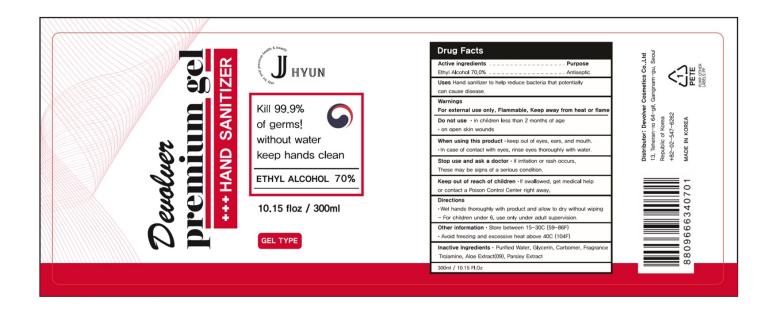
 Avoid freezing and excessive heat above 40C (104F)
Inactive Ingredients - Purified Water, Glycerin, Carbomer, Fragrand mine, Aloe Extract(09), Parsley Extract

350ml / 11,83 Fl,Oz

Significant States of the Company of Distributor: Devolver Cc 13, Teheran-ro 64-gil, Ga Republic of Korea +82-02-547-6262







# **DEVOLVER PREMIUM GEL**

alcohol gel

# **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:75001-201

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70.00075 mL in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)			
TROLAMINE (UNII: 9O3K93S3TK)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
PETRO SELINUM CRISPUM (UNII: 1WZA4Y92EX)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			

]	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75001-201- 01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020		
2	NDC:75001-201- 02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020		
3	NDC:75001-201- 03	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020		

4	NDC:75001-201- 04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/08/2020	
5	NDC:75001-201- 05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
6	NDC:75001-201- 06	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
7	NDC:75001-201- 07	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	
8	NDC:75001-201- 08	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/08/2020		

# Labeler - Devolver Cosmetics Co., Ltd (695733244)

# Registrant - Devolver Cosmetics Co., Ltd (695733244)

Establishment				
Name	Address	ID/FEI	Business Operations	
Devolver Cosmetics Co., Ltd		695733244	manufacture(75001-201)	

Revised: 6/2020 Devolver Cosmetics Co., Ltd