

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.

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

devolver premium gel

only for professional health & beauty
JJHYUN

++ HAND SANITIZER

Kill More Than 99.9% of Germs! keep hands clean

ETHYL ALCOHOL 70%

2.02 fl oz / 60 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 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, Aloe Extract(09), Parsley Extract	
60mL / 2.02 Fl. Oz.	

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

1 PETE
PAPER OTHER
LABELS PP

8809666340497

devolver premium gel

only for professional health & beauty
JJHYUN

++ HAND SANITIZER

Kill More Than 99.9% of Germs! keep hands clean

ETHYL ALCOHOL 70%

3.38 fl oz / 100 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 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, Aloe Extract(09), Parsley Extract	
100mL / 3.38 Fl. Oz.	

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

1 PETE
PAPER OTHER
LABELS PP

8809666340503

devolver premium gel



++ HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHYL ALCOHOL 70%

8.0 fl oz / 236 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	
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) Fragrance	
Inactive Ingredients - Purified Water, Glycerin, Carbomer, Fragrance, Triethanolamine, Aloe Extract(09), Parsley Extract	
236ml / 8.0 Fl. Oz	



Distributor: Devolver Cosmetics Co., Ltd
13, Toheam-ro 64-gil, Gangnam-gu, Seoul,
Republic of Korea
+82-02-547-6262



MADE IN KOREA

devolver premium gel



++ HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHYL ALCOHOL 70%

16.9 fl oz / 500 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 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, Triethanolamine, Aloe Extract(09), Parsley Extract	
500ml / 16.90 Fl. Oz	



Distributor: Devolver Cosmetics Co., Ltd
13, Toheam-ro 64-gil, Gangnam-gu, Seoul,
Republic of Korea
+82-02-547-6262



MADE IN KOREA

levolver premium gel



++ HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHYL ALCOHOL 70%

1 GAL (3.78 L)



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 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, Aloe Extract(09), Parsley Extract	
1 GAL (3,78 L)	

MADE IN KOREA

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

DEVOLVER PREMIUM GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item 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 HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PETROSELINUM CRISPUM (UNII: 1WZA4Y92EX)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

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	

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: 5/2020

Devolver Cosmetics Co., Ltd