

DEVOLVER HAND SANITIZER- 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.

75001-010

ACTIVE INGREDIENT

Active ingredients

ETHANOL 70%

INACTIVE INGREDIENT

Inactive ingredients

Water, Glycerin, Carbomer, Trolamine, Aloe Extract, Parsley Extract, Orange Oil, Limonene

PURPOSE

Purpose: ANTISEPTIC

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

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

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

Other information

Other information

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

PACKAGE LABEL - Devolver Hand Sanitizer Gel 100mL



DEVOLVER GEL

HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHANOL 70%

3.38 fl oz / 100ml

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 • Water, Glycerin, Carbomer, Triethylamine, Aloe Extract, Parsley Extract, Orange Oil, Limonene
Distributor: Devolver Cosmetics Co.,Ltd 94-3 Yongjeong gyeongje-ro 1-Gil, Gunnae-myeon, Pocheon-si, Gyeonggi-do, 11154 Republic of Korea +82 -02-547-6262
Manufacturer: Skin n Skin Co., Ltd. 14-1 Donyu 2-ro, Munsan-eup, Paju, 10832, Korea 100mL / 3,38 Fl. Oz.



PETE
PUMP & OTHER
LABELS 1 PP

MADE IN KOREA



8809115169761

PACKAGE LABEL - Devolver Hand Sanitizer Gel 236mL



DEVOLVER GEL

HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHANOL 70%

8,0 floz / 236 ml

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

• Water, Glycerin, Carbomer, Triethylamine, Aloe Extract, Parsley Extract, Orange Oil, Limonene

Distributor: Devolver Cosmetics Co.,Ltd

94-3 Yongjeong gyeongje-ro 1-Gil,
Gunnae-myeon, Pocheon-si, Gyeonggi-do,
11154 Republic of Korea
+82 -02-547-6262

Manufacturer: Skin n Skin Co., Ltd.

14-1 Donyu 2-ro, Munsan-eup, Paju, 10832, Korea
236mL / 8,0 FL Oz




8809666340411



PETE
PLASTIC BOTTLES AND
LABELS ONLY
MADE IN KOREA

PACKAGE LABEL - Devolver Hand Sanitizer Gel 500mL



DEVOLVER GEL

HAND SANITIZER

Kill More Than 99.9% of Germs!
keep hands clean

ETHANOL 70%

16.9 floz / 500 ml

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)

Inactive Ingredients -Water, Glycerin, Carbomer, Triethylamine, Aloe Extract, Parsley Extract, Orange Oil, Limonene

Manufacturer: Skin n Skin Co., Ltd.
14-1 Donyu 2-ro, Munsan-eup, Paju, 10832, Korea

500mL / 16.90 Fl. Oz

Distributor: Devolver Cosmetics Co.,Ltd
94-3 Yongjeong-gyeongja-ro 1-Cll
Gunsan-myeon, Pochon-gun, Gyeongju-do,
71154, Republic of Korea
+82-54-547-4262



8809115169785

MADE IN KOREA

Package Label

Medicinal Ingredient Ethyl alcohol (Ethanol) ... 70%

Recommended Use Antiseptic (skin) cleanser. Medicated (skin) cleanser. Antibacterial (skin) cleanser. Kills harmful bacteria/germs. Effective in destroying (harmful) bacteria to provide antiseptic cleansing. For personal hand hygiene to help prevent the spread of bacteria.

Recommended Dose Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product. For occasional and personal domestic use.

Cautions and Warnings For external use only. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask health care practitioner if irritation develops. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Flammability warning - Keep away from open flame and sources of heat.





Hand Sanitizer

Kills harmful bacteria/germs

NDC 75001-010-04
70% Etyle Alcohol

500 ML 16.9 FL OZ

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, Fragrances Triethylamine, Aloe Extract(99), Parsley Extract

500mL / 16.90 Fl. Oz



8809666340527

MADE IN KOREA

Distributor: Devolver Cosmetics Co.,Ltd
13, Teheran-ro 64-gil, Gangnam-gu, Seoul,
Republic of Korea
+82-02-547-4262



PUMP-OTHER LABELS-PP

Medicinal Ingredient Ethyl alcohol (Ethanol) ... 70%

Recommended Use Antiseptic (skin) cleanser. Medicated (skin) cleanser. Antibacterial (skin) cleanser. Kills harmful bacteria/germs. Effective in destroying (harmful) bacteria to provide antiseptic cleansing. For personal hand hygiene to help prevent the spread of bacteria.

Recommended Dose Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product. For occasional and personal domestic use.

Cautions and Warnings For external use only. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask health care practitioner if irritation develops. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Flammability warning - Keep away from open flame and sources of heat.



Hand Sanitizer

Kills harmful bacteria/germs

NDC 75001-010-05
70% Etyle Alcohol

500 ML 16.9 FL OZ

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, Fragrances Triethylamine, Aloe Extract(99), Parsley Extract

500mL / 16.90 Fl. Oz



8809666340527

MADE IN KOREA

Distributor: Devolver Cosmetics Co.,Ltd
13, Teheran-ro 64-gil, Gangnam-gu, Seoul,
Republic of Korea
+82-02-547-4262



PUMP-OTHER LABELS-PP

Medicinal Ingredient Ethyl alcohol (Ethanol) ... 70%

Recommended Use Antiseptic (skin) cleanser. Medicated (skin) cleanser. Antibacterial (skin) cleanser. Kills harmful bacteria/germs. Effective in destroying (harmful) bacteria to provide antiseptic cleansing. For personal hand hygiene to help prevent the spread of bacteria.

Recommended Dose Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older: Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product. For occasional and personal domestic use.

Cautions and Warnings For external use only. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask health care practitioner if irritation develops. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Flammability warning - Keep away from open flame and sources of heat.

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

8809666340527
MADE IN KOREA

70%
Etyle Alcohol

+ HAND SANITIZER
Kills harmful bacteria/germs
NDC 75001-010-06
Devolver GEL
500 ML 16.9 FL OZ

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	
500mL / 16.90 FL. Oz	

DEVOLVER HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75001-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE (UNII: V5VD430YW9)	
PARSLEY (UNII: 58FMD0Q0EV)	
ORANGE OIL (UNII: AKN3KSD11B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75001-010-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:75001-010-02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
3	NDC:75001-010-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

4	NDC:75001-010-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/09/2020	
5	NDC:75001-010-05	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/09/2020	
6	NDC:75001-010-06	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/09/2020	

Marketing Information

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

Labeler - Devolver Cosmetics Co.,Ltd (695733244)

Registrant - Devolver Cosmetics Co.,Ltd (695733244)

Establishment

Name	Address	ID/FEI	Business Operations
Skin n Skin Co., Ltd.		631090037	manufacture(75001-010)

Revised: 6/2020

Devolver Cosmetics Co.,Ltd