

## **DEVOLVER PREMIUM TISSUE- alcohol liquid**

**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 75%

### **Purpose**

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, Hydroxy Acetophenone, Cetylpyridinium Chloride, Citric Acid, Butylene Glycol, Aloe ferox leaf extract, Fragrance (Lime)

### Package Label





# DEVOLVER

COSMETICS

<b>Drug Facts</b>	
<b>Active ingredients</b> ----- <b>Purpose</b>	
Ethyl Alcohol 75.0% ----- Antiseptic	
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> <b>For external use only, Flammable, Keep away from heat or flame</b>	
<b>Do not use</b> · in children less than 2 months of age · on open skin wounds	
<b>When using this product</b> · keep out of 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 right away.
<b>Directions</b> · Wet hands thoroughly with product and allow to dry without wiping – For children under 6, use only under adult supervision.
<b>Other information</b> · Store between 15–30C (59–86F) · Avoid freezing and excessive heat above 40C (104F)
<b>Inactive Ingredients</b> · Ethyl Alcohol, Water, Glycerin, Hydroxy Acetophenone, Cetylpyridinium Chloride, Citric Acid, Butylene Glycol, Aloe ferox leaf extract ,Fragrance

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



8809666340633



**PETE**  
PUMP-OTHER  
LABELS:PP

**DEVOLVER**  
COSMETICS

**devolver**   
**premium tissue**

75% ETHANOL

20ea (100g)

OPEN

Kill More Than 99.9% of Germs!  
keep hands clean



# Devolver

COSMETICS

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<b>Active ingredients</b> ----- <b>Purpose</b> Ethyl Alcohol 75.0% ----- Antiseptic	<b>Keep out of reach of children</b> • If swallowed, get medical help or contact a Poison Control Center right away.
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease.	<b>Directions</b> • Wet hands thoroughly with product and allow to dry without wiping – For children under 6, use only under adult supervision.
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b>	<b>Other information</b> • Store between 15–30C (59–86F) • Avoid freezing and excessive heat above 40C (104F)
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	<b>Inactive Ingredients</b> • Ethyl Alcohol, Water, Glycerin, Hydroxy Acetophenone, Cetylpyridinium Chloride, Citric Acid, Butylene Glycol, Aloe ferox leaf extract ,Fragrance
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## DEVOLVER PREMIUM TISSUE

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75001-204
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE FEROX LEAF (UNII: 0D145J8EME)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
LIME (CALCIUM OXIDE) (UNII: C7X2M0VVNH)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75001-204-01	100 g in 1 POUCH; Type 0: Not a Combination Product	05/17/2020	
2	NDC:75001-204-02	100 g in 1 POUCH; Type 0: Not a Combination Product	05/17/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/17/2020	

**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(75001-204)

Revised: 5/2020

Devolver Cosmetics Co., Ltd