DEVOLVER PREMIUM-SPRAY- 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.

Active ingredient

Ethyl Alcohol 75%

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

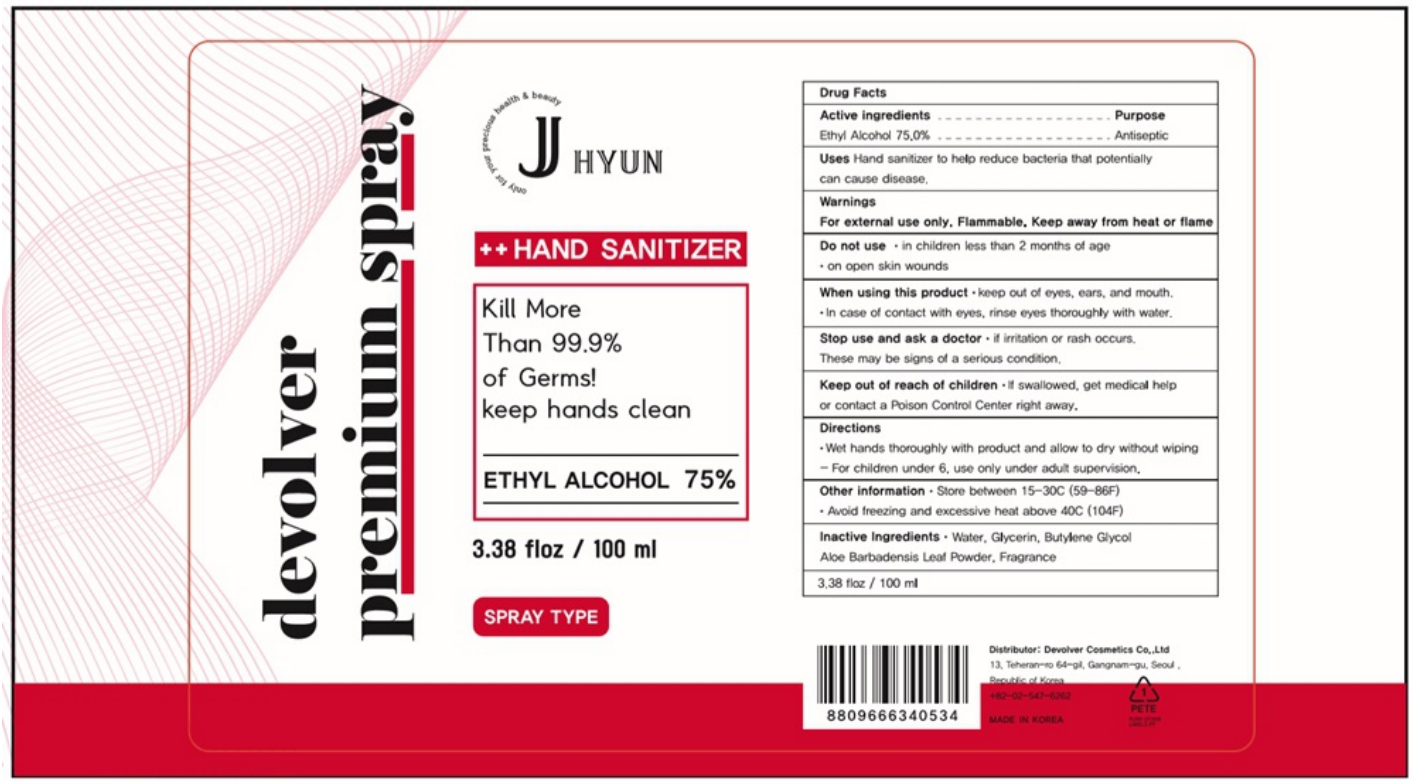
Store between 15-30C (59-86F)

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

Inactive ingredients

Water, Glycerin, Butylene Glyol, Aloe Barbadensis Leaf Powder, Fragrance

Package Label



DEVOLVER PREMIUM-SPRAY

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75001-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75.0006 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75001-202-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/08/2020	
2	NDC:75001-202-02	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/08/2020	
3	NDC:75001-202-03	500 mL in 1 BOTTLE, SPRAY; 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(75001-202)

Revised: 5/2020 Devolver Cosmetics Co., Ltd