

**EDEW CLAIRE PERFECT HAND DISINFECTION- alcohol gel
MYUNG COSMETIC**

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 70.0 % v/v

INACTIVE INGREDIENTS

Water, Triethanolamine, Glycerin, Carbomer, Polysorbate 20, Tocopheryl Acetate, Perfume

PURPOSE

Antiseptic

WARNINGS

1. Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin (Irritation may occur)

2. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

3. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

- Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema
- Skin irritation symptoms

4. Other precautions

- For external use only (do not swallow).
- Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.
- Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).
- If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.
- Do not use sealed bandages, cast bandages, or packs as they may cause irritation.
- Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.
- Use only for the intended purposes.

5. Precautions for storage

- Keep away from direct sunlight and do not expose the product to heating devices or flame.
- After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.
- Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

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

Uses

Disinfection of hands and skin

Directions

Take an appropriate amount on your hands and rub thoroughly to dry.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

 <p>edew claire skin science institute</p> <p>PERFECT HAND DISINFECTION GEL</p> <p>Hand Sanitizer</p> <p>500ml / 16.90 Fl. Oz.</p> <p>Fast and effective Moisturizer with Vitamin E Ethyl Alcohol 70%</p>	<p>EDEWCLAIRE PERFECT HAND DISINFECTION GEL</p> <p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredients Ethyl alcohol 70.0% v/v.....</td> <td>Purpose Antiseptic</td> <td rowspan="2"> <ul style="list-style-type: none"> Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. Use only for the intended purposes. </td> </tr> <tr> <td colspan="2"> Uses Disinfection of hands and skin </td> </tr> <tr> <td colspan="3"> Warnings 1. Do not use the product on the following areas: Around the eyes and ears, in the mouth, large body parts and damaged skin(irritation may occur) </td> </tr> <tr> <td colspan="3"> 2. Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away. </td> </tr> <tr> <td colspan="3"> 3. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. ● Hypersensitivity symptoms, e.g.rash, erythema, itchiness, and edema ● Skin irritation symptoms </td> </tr> <tr> <td colspan="3"> 4. Other precautions ● For external use only (do not swallow). ● Avoid contact with eyes, if contact occurs, wash with clean water and consult a doctor or pharmacist. ● Be careful not to inhale vapors in case of extended or prolonged use.(Repeating inhaling of large amount of ethenol vapor may cause irritation of the mucous membranes and headaches). ● If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. ● Do not use sealed bandages, cast bandages, or packs as they may cause irritation. </td> </tr> <tr> <td colspan="2"> Directions Take an appropriate amount on your hands and rub thoroughly to dry. </td> <td rowspan="2">  </td> </tr> <tr> <td colspan="2"> Inactive Ingredients Water, Triethanolamine, Glycerin, Carbomer, Polysorbate 20, Tocopheryl Acetate, Perfume </td> </tr> <tr> <td colspan="3"> Eva Claire Cosmetics Co., Ltd. 31-3 Shinchon Nam-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, S. Korea(Tel : 82-2-830-0071~2) </td> </tr> <tr> <td colspan="3"> MYUNG COSMETIC 24-33, Hambangmoe-ro, 377beon-gil, Namdong-gu, Incheon, S. Korea </td> </tr> <tr> <td colspan="3"> Net Wt: 500mL / 16'90 Fl. Oz. Made in Korea </td> </tr> </table>	Active Ingredients Ethyl alcohol 70.0% v/v.....	Purpose Antiseptic	<ul style="list-style-type: none"> Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. Use only for the intended purposes. 	Uses Disinfection of hands and skin		Warnings 1. Do not use the product on the following areas: Around the eyes and ears, in the mouth, large body parts and damaged skin(irritation may occur)			2. Keep out of reach of children, if swallowed, get medical help or contact a Poison Control Center right away.			3. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist. ● Hypersensitivity symptoms, e.g.rash, erythema, itchiness, and edema ● Skin irritation symptoms			4. Other precautions ● For external use only (do not swallow). ● Avoid contact with eyes, if contact occurs, wash with clean water and consult a doctor or pharmacist. ● Be careful not to inhale vapors in case of extended or prolonged use.(Repeating inhaling of large amount of ethenol vapor may cause irritation of the mucous membranes and headaches). ● If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. ● Do not use sealed bandages, cast bandages, or packs as they may cause irritation.			Directions Take an appropriate amount on your hands and rub thoroughly to dry.			Inactive Ingredients Water, Triethanolamine, Glycerin, Carbomer, Polysorbate 20, Tocopheryl Acetate, Perfume		Eva Claire Cosmetics Co., Ltd. 31-3 Shinchon Nam-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, S. Korea(Tel : 82-2-830-0071~2)			MYUNG COSMETIC 24-33, Hambangmoe-ro, 377beon-gil, Namdong-gu, Incheon, S. Korea			Net Wt: 500mL / 16'90 Fl. Oz. Made in Korea		
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EDEW CLAIRE PERFECT HAND DISINFECTION

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74777-090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
Glycerin (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74777-090-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - MYUNG COSMETIC (688222692)**Registrant** - MYUNG COSMETIC (688222692)**Establishment**

Name	Address	ID/FEI	Business Operations
MYUNG COSMETIC		688222692	manufacture(74777-090)

Revised: 5/2020

MYUNG COSMETIC