

**CELLAPY PURE DERMA SANITIZER- alcohol gel**  
**GM Holdings 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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**Drug Facts**

**ACTIVE INGREDIENT**

ACTIVE INGREDIENT: Ethyl Alcohol 76% v/v

**INACTIVE INGREDIENT**

INACTIVE INGREDIENT:

Water, Butylene Glycol, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Polyoxyethylene Hydrogenated Castor oil, Fragrance

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

**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.

For use when soap and water are not available

## Directions

Directions:

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

Other information:

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

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

 <p>Helps Reduce Bacteria</p> <p><b>Cellapy</b></p> <p><b>Pure Derma Sanitizer</b></p> <p>No need for soap and water, Convenient and simple to use hand sanitizer</p> <p>Disinfection   Sterilization Effects</p> <p>Mild   Moist   Clean</p> <p>500ml   16.90 fl.oz.</p> <p>Do Not Consume</p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active Ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Ethyl Alcohol 76% v/v</td> <td>Antiseptic</td> </tr> </table> <p><b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul> <p><b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p><b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• Store between 15-30°C (59-86°F)</li> <li>• Avoid freezing and excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive Ingredients</b> Water, Butylene Glycol, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Polyoxyethylene Hydrogenated Castor oil, Fragrance</p> <p><b>Distributor:</b> GM Holdings Co., Ltd. Secho-gu, Gangnam-daero 331 (Kwangil Plaza 11th Floor), Seoul, South Korea</p> <p><b>Questions or Comments?</b> Call +82 070 5066 4772</p> <p><b>Net Wt</b> 500ml / 16.90 Fl. Oz.</p> <p>Made in Korea</p>  <p>8 809386 603872</p>	<b>Active Ingredient</b>	<b>Purpose</b>	Ethyl Alcohol 76% v/v	Antiseptic
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Ethyl Alcohol 76% v/v	Antiseptic				

## CELLAPY PURE DERMA SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69278-112
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69278-112-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

## Marketing Information

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

**Labeler** - GM Holdings Co., Ltd (688439958)

**Registrant** - GM Holdings Co., Ltd (688439958)

## Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(69278-112)

Revised: 4/2020

GM Holdings Co., Ltd