

**CUBRETE ANTISEPTIC HAND SANITIZER- ethyl alcohol gel**  
**Frozen Wheels, Llc**

*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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**CUBRE T® HAND SANITIZER GEL**

***Drug Facts***

***Active ingredient***

Ethyl alcohol 70%v/v

***Purpose***

Antimicrobial

***Uses***

- Hand Sanitizer to help reduce bacteria that potentially cause disease.
- For use when soap and water are not available.

***Warnings***

***Flammable***

- Keep away from fire or flame.
- For external use only.

***When using this product***

- Do not use it in or near the eyes.
- In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if skin irritation occurs.

Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.

***Directions***

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

***Other information***

- Store below 110°F (43°C)
- May discolor certain fabrics

***Inactive Ingredients*** Triethanolamine, Carbomer, Polysorbate, Water, Glycerin.

***Questions?***

+52 1 56 1876 7678    [info@cubret.mx](mailto:info@cubret.mx)

***Alcohol Based***

**Manufactured by:** Corporativo Cubrete, S.A. de C.V. Calzada las Aguilas 1709, Interior B, Lomas de

Guadalupe, Alvaro Obregon, C.P.01720 Made in Mexico

Imported by: Frozen Wheels, LLC 16565 NW 15th Ave. Miami, FL 33169

HECHO EN

MEXICO

### Packaging

Package 50 mL



#### Drug Facts

<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70%w/v	Antimicrobiano

**Uses**

- Hand Sanitizer to help reduce bacteria that potentially cause disease. • For use when soap and water are not available.

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**Inactive Ingredients**

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Made in Mexico

**Imported by:**  
Frozen Wheels, LLC  
16565 NW 15th Ave.  
Miami, FL 33169



Package 125 mL

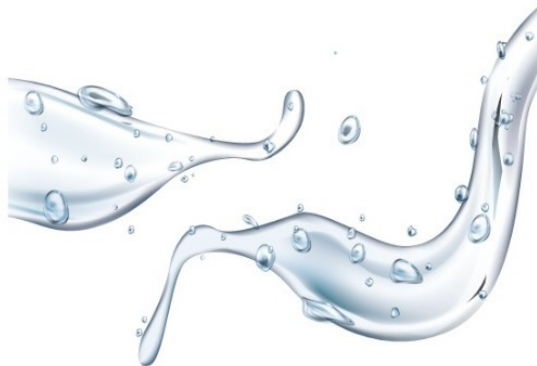


Alcohol Based  
Ethyl Alcohol 70%

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70%w/v	Antimicrobial
<b>Uses</b>	
• Hand Sanitizer to help reduce bacteria that potentially cause disease. • For use when soap and water are not available.	
<b>Warnings</b>	
<b>Flammable</b>	
• Keep away from fire or flame. • For external use only.	
<b>When using this product</b>	
• Do not use it in or near the eyes. • In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if skin irritation occurs.	
Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.	
<b>Directions</b>	
• Put enough product in your palm to cover hands and rub hands together briskly until dry.	
• Children under 6 years of age should be supervised when using this product.	
<b>Other information</b>	
• Store below 110°F (43°C) • May discolor certain fabrics	
<b>Inactive Ingredients</b> Triethanolamine, Carbomer, Polysorbate, Water, Glycerin.	
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Net. wt. 4.2 fl oz (125ml)

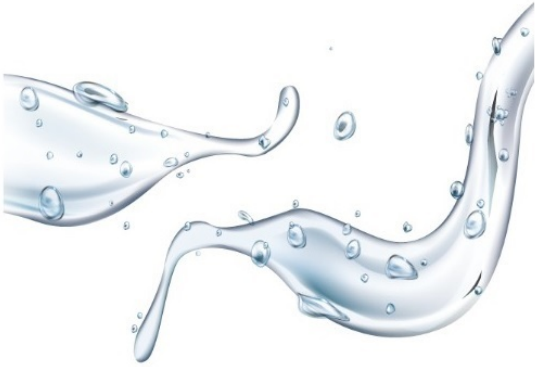
Package 250 mL





## HAND SANITIZER GEL

Alcohol Based  
Ethyl Alcohol 70%



Net. wt. 8.4 fl oz (250ml)

Package 500 mL



## HAND SANITIZER GEL

Alcohol Based  
Ethyl Alcohol 70%



### Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% <i>v/v</i>	Antimicrobial
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Hand Sanitizer to help reduce bacteria that potentially cause disease.</li> <li>For use when soap and water are not available.</li> </ul>	
<b>Warnings</b>	
<b>Flammable</b>	
<ul style="list-style-type: none"> <li>Keep away from fire or flame. - For external use only.</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>Do not use it in or near the eyes. - In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if skin irritation occurs.</li> <li>Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Put enough product in your palm to cover hands and rub hands together briskly until dry.</li> <li>Children under 6 years of age should be supervised when using this product.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store below 110°F (43°C) - May discolor certain fabrics</li> </ul>	
<b>Inactive Ingredients</b> Triethanolamine, Carbomer, Polysorbate, Water, Glycerin.	
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### Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% <i>v/v</i>	Antimicrobial
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Hand Sanitizer to help reduce bacteria that potentially cause disease.</li> <li>For use when soap and water are not available.</li> </ul>	
<b>Warnings</b>	
<b>Flammable</b>	
<ul style="list-style-type: none"> <li>Keep away from fire or flame. - For external use only.</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>Do not use it in or near the eyes. - In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if skin irritation occurs.</li> <li>Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Put enough product in your palm to cover hands and rub hands together briskly until dry.</li> <li>Children under 6 years of age should be supervised when using this product.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store below 110°F (43°C) - May discolor certain fabrics</li> </ul>	
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Net. wt. 16.8 fl oz (500ml)

## Packaging

Package 1L



HAND SANITIZER GEL

Alcohol Based  
Ethyl Alcohol 70%



Net. wt. 33.8 fl oz (1L)

Package 4L

### Drug Facts

<b>Active ingredient</b> Ethyl alcohol 70%v/v	<b>Purpose</b> Antimicrobial
<b>Uses</b> - Hand Sanitizer to help reduce bacteria that potentially cause disease. - For use when soap and water are not available.	
<b>Warnings</b> <b>Flammable</b> - Keep away from fire or flame. - For external use only.	
<b>When using this product</b> - Do not use it in or near the eyes. - In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation occurs. Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.	
<b>Directions</b> - Put enough product in your palm to cover hands and rub hands together briskly until dry. - Children under 6 years of age should be supervised when using this product.	
<b>Other information</b> - Store below 110°F (43°C) - May discolor certain fabrics	
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# HAND SANITIZER GEL

Alcohol Based  
Ethyl Alcohol 70%



Net wt. 135.2 fl oz (4L)

## Drug Facts

<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70%v/v .....	Antimicrobial

<b>Uses</b>
<ul style="list-style-type: none"> <li>• Hand Sanitizer to help reduce bacteria that potentially cause disease.</li> <li>• For use when soap and water are not available.</li> </ul>

<b>Warnings</b>
<b>Flammable</b> <ul style="list-style-type: none"> <li>• Keep away from fire or flame. • For external use only.</li> </ul>

<b>When using this product</b>
<ul style="list-style-type: none"> <li>• Do not use it in or near the eyes. • In case of contact, rinse eyes thoroughly with water.</li> </ul>

Stop use and ask a doctor if skin irritation occurs.  
 Keep out of reach of children. If swallowed, get medical help in a Poison Control Center immediately.

<b>Directions</b>
<ul style="list-style-type: none"> <li>• Put enough product in your palm to cover hands and rub hands together briskly until dry.</li> <li>• Children under 6 years of age should be supervised when using this product.</li> </ul>

<b>Other information</b>
<ul style="list-style-type: none"> <li>• Store below 110°F (43°C) • May discolor certain fabrics</li> </ul>

<b>Inactive Ingredients</b>
Triethanolamine, Carbomer, Polysorbate, Water, Glycerin.

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## CUBRETE ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77031-105
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77031-105-02	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
2	NDC:77031-105-04	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
3	NDC:77031-105-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
4	NDC:77031-105-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	
5	NDC:77031-105-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020	

6	NDC:77031-105-01	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2020
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/08/2020	

**Labeler** - Frozen Wheels, Llc (069055731)

Revised: 7/2020

Frozen Wheels, Llc