





**MEGACLEAN HAND SANITIZER- ethanol gel**  
**MEGACITY GROUP 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.*

**MegaClean HAND SANITIZER 300 mL**  
**77799-370-01**

 <p>The image shows the packaging for MegaClean Hand Sanitizer. It is a green and white design. At the top, it says 'MegaClean HAND SANITIZER' with a logo of a hand being washed. Below that, it says '70% Alcohol KILLS 99.9% OF GERMS*'. A circular badge says 'ANTIBACTERIAL'. At the bottom, it says 'NET WEIGHT 10.14 fl. oz   300 ml' and '100% Recyclable Container'. It also mentions 'Distributed by MEGACITY GROUP LLC For United States of America' and a caution: 'Caution: Do not drink or ingest. For external use only.'</p>	<table border="1"> <tr> <td colspan="2"><b>Drug Facts</b></td> </tr> <tr> <td><b>Active ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Ethanol 70% v/v</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2">A hand sanitizing gel that sanitizes your hands clean without water and soap, with no stickiness or residue left.</td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2">For external use only. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use:</td> </tr> <tr> <td colspan="2">■ in children less than 2 months of age ■ on open skin wounds</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="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="2"><b>Directions</b></td> </tr> <tr> <td colspan="2">■ Apply on your hands and massage thoroughly until it dries.</td> </tr> <tr> <td colspan="2">■ Supervise children under 6 years of age when using this product to avoid swallowing.</td> </tr> <tr> <td colspan="2">■ Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.)</td> </tr> <tr> <td colspan="2">■ This product is intended only for hand sanitizing.</td> </tr> <tr> <td colspan="2">■ Airtight Container.</td> </tr> <tr> <td colspan="2">■ Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.</td> </tr> <tr> <td colspan="2">■ Do not use over bandages, castings, etc. as irritation may occur.</td> </tr> <tr> <td colspan="2"><b>Other information</b></td> </tr> <tr> <td colspan="2">■ Store between 1–30°C (33.8–86°F)</td> </tr> <tr> <td colspan="2">■ Avoid freezing and excessive heat above 40°C(104°F)</td> </tr> <tr> <td colspan="2">*Effective at eliminating more than 99.99% of many common harmful germs &amp; bacteria in as little as 15 seconds.</td> </tr> <tr> <td colspan="2"><b>Inactive ingredients</b></td> </tr> <tr> <td colspan="2">Water, Glycerin, Triethanolamine, Carbomer, Propylene Glycol, Aminomethyl Propanol</td> </tr> <tr> <td colspan="2">Product Made in Korea Distributed by MEGACITY GROUP LLC 7901 CORAL WAY MIAMI, FL 33155</td> </tr> <tr> <td colspan="2">  </td> </tr> </table>	<b>Drug Facts</b>		<b>Active ingredient</b>	<b>Purpose</b>	Ethanol 70% v/v	Antiseptic	<b>Uses</b>		A hand sanitizing gel that sanitizes your hands clean without water and soap, with no stickiness or residue left.		<b>Warnings</b>		For external use only. 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.		<b>Directions</b>		■ Apply on your hands and massage thoroughly until it dries.		■ Supervise children under 6 years of age when using this product to avoid swallowing.		■ Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.)		■ This product is intended only for hand sanitizing.		■ Airtight Container.		■ Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.		■ Do not use over bandages, castings, etc. as irritation may occur.		<b>Other information</b>		■ Store between 1–30°C (33.8–86°F)		■ Avoid freezing and excessive heat above 40°C(104°F)		*Effective at eliminating more than 99.99% of many common harmful germs & bacteria in as little as 15 seconds.		<b>Inactive ingredients</b>		Water, Glycerin, Triethanolamine, Carbomer, Propylene Glycol, Aminomethyl Propanol		Product Made in Korea Distributed by MEGACITY GROUP LLC 7901 CORAL WAY MIAMI, FL 33155			
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**MEGACLEAN HAND SANITIZER**

ethanol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77799-370
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	210 mL in 300 mL

**Inactive Ingredients**

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77799-370-01	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/31/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2020	

**Labeler** - MEGACITY GROUP LLC (094579228)**Establishment**

Name	Address	ID/FEI	Business Operations
BL Cosmetic Co., Ltd		695735124	manufacture(77799-370)

Revised: 5/2020

MEGACITY GROUP LLC