

**HAND DEFENDER- alcohol gel**  
**Gm Integraciones y Soluciones en Control, S.A. de C.V.**

*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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**Active Ingredient**

Alcohol 70% v/v.

**Purpose**

Antiseptic

**Uses**

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

**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**

- 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**

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

**Inactive ingredients**

Purified Water, Glycerin, Carbopol, Triethanolamine

**Product Label**



# Alcohol Antiseptic 70% Topical Solution

**Hand Sanitizer**  
Non-sterile Solution

125 ML (4.22 FL OZ)

<b>DRUG FACTS</b>	
<i>Active ingredient[s]</i> Alcohol 70% v/v.....	<i>Purpose</i> .....Antiseptic
<i>Use[s]</i> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<i>Warnings</i> <b>For external use only. Flammable. Keep away from heat or flame.</b>	
<i>Do not use</i> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<i>Directions</i> • 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.	
<i>Other information</i> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<i>Inactive ingredients:</i> Carbopol, Glycerin, Purified Water USP, Triethanolamine.	

**MADE IN MEXICO**  
**GEL ANTIBACTERIAL MÉXICO**  
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53398 Naucalpan de Juárez, Méx  
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Expiration dating period  
Batch number

**ITEM #**  
barcode

# HAND DEFENDER

alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77377-001
<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
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77377-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
2	NDC:77377-001-02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
3	NDC:77377-001-03	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
4	NDC:77377-001-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
5	NDC:77377-001-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
6	NDC:77377-001-06	540 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
7	NDC:77377-001-07	700 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
8	NDC:77377-001-08	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
9	NDC:77377-001-09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
10	NDC:77377-001-10	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
11	NDC:77377-001-11	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
12	NDC:77377-001-12	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
13	NDC:77377-001-13	220000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
14	NDC:77377-001-14	1000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
15	NDC:77377-001-	200000 mL in 1 BOTTLE; Type 0: Not a Combination	05/08/2020	

15	Product	05/08/2020	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	05/08/2020	

**Labeler** - Gm Integraciones y Soluciones en Control, S.A. de C.V. (812758685)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Gm Integraciones y Soluciones en Control, S.A. de C.V.		812758685	manufacture(77377-001)

Revised: 5/2020

Gm Integraciones y Soluciones en Control, S.A. de C.V.